EXHIBIT 5

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	M.D.L. No. 1456 Civil Action No. 01-12257-PBS Judge Patti B. Saris

REPORT OF INDEPENDENT EXPERT

PROFESSOR ERNST R. BERNDT

TO JUDGE PATTI B. SARIS

FEBRUARY 9, 2005

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I. INTRODUCTION

A. Qualifications

1. My name is Ernst R. Berndt. I am the Louis B. Seley Professor of Applied Economics at the Sloan School of Management, Massachusetts Institute of Technology. I have been a Professor of Applied Economics at MIT since 1980. From 1992 to 1995, I served as Area Head of the Applied Economics, Finance and Accounting faculty area at MIT's Sloan School of Management. I am also a Research Associate at the National Bureau of Economic Research, serve as Director of its Program on Technological Change and Productivity Measurement, and am an Adjunct Professor at the Harvard Medical School, Division of Health Care Policy. In 2004 I was named Co-Director of the Biomedical Enterprise Program, a joint degree-granting program at the Harvard-MIT Division of Health Sciences and Technology and the MIT Sloan School of Management. I am an elected Fellow of the Econometric Society, and have been awarded an honorary doctorate degree from Uppsala University in Sweden. My professional qualifications are described in my curriculum vitae, which is attached as Attachment A to this report.

2. In the last fifteen years, a major focus of my academic research has been on health economics and the economics of the pharmaceutical and biotech industries. I have studied the impacts of marketing (i.e., direct-to-consumer advertising, medical journal advertising, physician detailing, and physician sampling) on sales of pharmaceutical drugs, the pricing patterns of generic and brand name prescription drugs, and prescription-only to over-the-counter switches, among other topics. A great deal of my research involves issues of price measurement. I have studied or currently am studying: the treatment of brand and generic drugs in pharmaceutical price indexes; price indexes for the treatment of certain illnesses, particularly mental disorders;

and the reliability and appropriate interpretation of the U.S. Bureau of Labor Statistics' price indexes for medical services and products. I am currently studying the process by which promising medicines move from pre-clinical and clinical development phases through the U. S. Food and Drug Administration approval process, factors affecting the differential rates of diffusion of new medicines across different countries, and policies that would provide incentives to biotech and pharmaceutical companies to develop medicines for third-world diseases.

3. In addition to my academic research, from 1996 to 2000 I served as an appointed representative of the American Economic Association to the Economics Advisory Committee of the U.S. Census Bureau, and from 1999 to 200 as its Co-Chair. From 1991 to 2000 I served as a member of the Advisory Committee on Service Statistics at Statistics Canada. Between 1999 and 2001, I was a member of the U. S. Committee on National Statistics and the National Academy of Sciences, Panel on the Conceptual, Measurement and Other Statistical Issues in Developing Cost-of-Living Indexes. Between 2000 and 2004, I also served as Chair of the newly created U. S. Federal Economic Statistics Advisory Committee, an interagency committee jointly formed by the U.S. Bureau of Labor Statistics, the U. S. Census Bureau, and the U. S. Bureau of Economic Analysis. Recently I finished a two-year term as a review panel member for the Methodology, Measurement and Statistics program at the National Science Foundation. From October 2003 through June 2004 I served on an unpaid Intermittent Detail to the U. S. Food and Drug Administration, Office of the Commissioner.

4. Over the years, I have served as an expert on a number of health care litigation matters, retained by counsel for branded pharmaceutical and biotech firms, generic pharmaceutical manufacturers, by third party payors, and by the Federal Trade Commission.

B. Nature of Assignment and Terms of Engagement

5. In a telephone conference call on November 23, 2004 involving United States District Court Judge Patti B. Saris and Counsel for Plaintiffs and Defendants (in the case In Re Pharmaceutical Industry Average Wholesale Price Litigation, relating to 01-CV-12257-PBS and 01-CV-339, MDL No. 1456, Civil Action No. 01-12257-PBS), I confirmed my commitment to serve "as an independent expert on the pharmaceutical industry for purposes of the motion of class certification".[1] The subsequent Court Order specified:

> "The Court will meet privately with Professor Berndt following the presentations to discuss the topics of the report he will write about the pharmaceutical industry. If the Court submits questions to Professor Berndt, copies will be placed on the record. Professor Berndt will submit his report in late January. The parties agreed that the Court will be allowed to speak with Professor Berndt privately to clarify the contents of his report. If Professor Berndt provides information beyond what is in the record, he will supplement his report. Provisions for payment of Dr. Berndt by both sides shall be handled by Eric Green, not the Court."[2]

6. I am being compensated at my normal consulting rate of $525 per hour, plus reasonable out of pocket expenses, with Plaintiffs' counsel contributing a 33 percent share, and defendants' counsel a 67 percent share.[3] Invoices have been sent by Berndt Associates LLC to plaintiffs' and defendants' counsels on January 3, 2005, and February 1, 2005.

7. As stipulated in the Court Order, I attended Plaintiffs' tutorial on Monday, December 6, 2004, and Defendants' tutorial on Tuesday, December 7, 2005. I met very briefly with Judge Saris and her clerk, Benjamin Halasz, following the December 7, 2005 tutorial. I met with both

[1] Court Order, email from Benjamin_Halasz@mad.uscourts.gov to berndt@rcn.com, dated Monday, January 24, 2005, containing transcription of Court Order entered November 23, 2004. Hereafter I refer to this as "Court Order".
[2] Court Order, *supra.*
[3] Letter from D. Scott Wise and Steven Berman to Dr. Ernst R. Berndt, Berndt Associates, Inc., dated November 18, 2004. Eric Green, Resolutions LLC, is a mediator.

Judge Saris and Mr. Halasz for about an hour on Monday, December 13, 2004, discussing in general the topics I would be addressing in my report. I met with Mr. Halasz for about 90 minutes on Thursday, January 27, 2005, and discussed with him the portions of the report I had preliminarily drafted, as well as topics and issues I planned to address in the final version of this report. Although I brought with me to that meeting and shared with Mr. Halasz a hard copy of my incomplete draft report, Mr. Halasz returned the copy to me as I left. The Court has therefore not had in its possession either a hard copy or electronic version of that incomplete draft report. I have had several email exchanges with Mr. Halasz involving general questions on meeting logistics, the legal status of certain allegations, and the Corrected Amended Master Consolidated Class Action Complaint.

C. Interpretation of My Assignment

8. This litigation has generated a voluminous amount of documentation. Judge Patti B. Saris has described the litigation as a "massive proposed class action".[4] I understand my assignment as an independent expert is to provide context, background, literature citation and analysis to assist the Court in efficiently interpreting information provided it by counsel for Defendants and counsel for Plaintiffs. I am also asked to outline what additional, if any, potentially material information has not been presented to the Court, particularly in the context of class certification issues involving commonality and typicality. I have approached this assignment as an academic endeavoring to be of service to the Court in undertaking a substantial research project, first attempting to understand the background, then delving into details, and finally, writing up the results of the analyses. That is the approach I have taken, albeit on an

[4] *Memorandum and Order,* United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, February 24, 2004, p. 1.

accelerated timetable. While my primary focus in this report is not on issues of merit, my background discussion and critiques in some instances may be interpreted as crossing that line.

D. Information Considered

9. In undertaking my analyses, I have considered information from a wide variety of sources. As appropriate, I reference these in the report when I rely on them directly. The information I considered includes documents provided through legal filings and the discovery process; tutorials presented to the court; third party data sources and industry reports; academic papers, government reports and scholarly writings; and research reports from investment analysts and industry trade publications.

E. Structure of the Report

10. I begin in Section II by providing a brief overview of Plaintiff's allegation, the role of AWP, as well as a summary of the methodology employed by Plaintiff's Expert Dr. Raymond S. Hartman. In Section III I discuss extensively the origin, evolution and persistence of AWP and the "spread" between AWP, the wholesale acquisition price ("WAC"), and actual acquisition prices. I do this separately for brand name/single source self-administered drugs, generic/multisource self-administered drugs, and physician-administered drugs, pointing out their similarities and especially their differences.[5] In this Section I also review public documents describing the discounts off AWP obtained by government and private sector payors, consider why it is that confusion concerning what AWP measures continues and persists, and briefly note other uses of AWP.

11. In Section IV, which constitutes a substantial portion of the report, I consider a variety of issues involving competition, price transparency, information flows and PBM management of

[5] While I understand that precise definitions of brand, generic, single source and multi-source drugs are complex, unless I state distinctions explicitly, for the purposes of this report I will largely overlook those complications.

purchases of self-administered drugs. In Section V I consider competition, price transparency, information flows and the rather different environment in which purchases of physician-administered drugs are managed. Finally, in Section VI I consider a number of specific issues dealing with class certification, and comment on the proposed methodology of Plaintiff's Expert Dr. Raymond S. Hartman.

II. OVERVIEW

A. The Complaint

12. In what Judge Patti B. Saris has called a "massive proposed class action", Plaintiffs have alleged that by setting and facilitating the publication of "average wholesale prices", forty-two pharmaceutical companies have fraudulently overstated actual acquisition costs for many prescription drugs, resulting in inflated payments for such drugs by consumers and beneficiaries of the federal Medicare Part B program (through coinsurance payments), private health and welfare plans, health insurers, self-insured employers and other end-payors for prescription drugs.[6] Plaintiffs have identified 321 drug entities (designated AWPIDs), including self-administered and physician-administered, branded (single-source and multi-source) and generic (multi-source), with allegedly inflated prices.[7] Defendant's expert Steven J. Young calls the proposed class size "enormous", noting that in 2003 there were over 350 Health Plans in the US covering over 197 million lives, entering into "innumerable" contracts involving many of the approximately 497,852 physicians, 55,001 pharmacies and 60 pharmaceutical benefit

[6] *Memorandum and Order,* United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, February 24, 2004, p. 1.
[7] *Memorandum and Order,* February 24, 2004, *supra*, pp. 1-2.

management firms.[8] Plaintiffs' expert Dr. Raymond S. Hartman simply calls the proposed class "large".[9]

13. In their December 17, 2004 amended motion for class certification, Plaintiffs have named end-payor classes as follows: (i) physician-administered drugs class (Medicare Part B co-pay and private system physician-administered drugs); (ii) self-administered and specialty pharmacy drugs class (third-party and co-payor class for self-administered drugs), further subdivided into (iia) brand name sub-class and (iib) generic sub-class; (iii) RICO class for self-administered and specialty drugs, further divided into (iiia) brand name sub-class and (iiib) generic sub-class. The proposed class period is January 1991 to the present.[10]

B. The Role of AWP

14. To knowledgeable industry observers, it has long been widely understood that in the US pharmaceutical industry the term "average wholesale price" (hereafter, "AWP") is a misnomer: it is not a measure of prices generally paid by wholesalers to manufacturers, it is not a measure of prices frequently paid by retail or mail order pharmacies to wholesalers, nor is it some average of these. I will document this below.

15. At least since the beginning of the widely publicized "Brand Name Drug Litigation" in 1994, it has been common knowledge among industry observers that brand pharmaceutical firms typically sell self-administered single-source drugs to wholesalers at a price known as "wholesale acquisition cost" ("WAC") that in most cases is 16.67% to 20% less than AWP; this

[8] *Declaration of Steven J. Young In Opposition to the Plaintiff's Motion for Class Certification*, United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, October 25, 2004, pp. 8-9.
[9] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification,* United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, December 16, 2004, p. 3.
[10] *Plaintiffs' Amended Motion for Class Certification*, United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, December 17, 2004, pp. 3-4.

implies that AWP is typically 20% to 25% greater than WAC.[11] Moreover, using various rebates and chargeback policies, brand pharmaceutical manufacturers have offered a variety of discounts to health care providers and pharmaceutical benefit management ("PBM") firms, frequently expressed as "AWP – x%" or "WAC ± y%", in return for favorable placement of their drug on the client's formulary, meeting market share or volume targets, and/or attaining other contractually specified goals.[12] In turn, providers and PBMs have contracted with pharmacy networks, reimbursing them for dispensing drugs, generally employing contractual terms such as "AWP – z%" plus a dispensing fee, and perhaps administrative fees.

16. If a contract involving branded single-source self-administered drugs were specified in terms of WAC rather than AWP, in most cases it has been straightforward to convert it to AWP terms, given the largely predictable relationships between AWP and WAC (although this AWP-WAC relationship is considerably more complex and variable with multisource brand and multisource generic drugs).[13] In this way, even though industry observers and academics have quipped that AWP stands for "Ain't What's Paid" rather than "Average Wholesale Price",[14] it is nonetheless the case that AWP has served as a reference or focal point, an industry standard for baseline reimbursement, and as such a fictional benchmark price from which discounts are frequently specified, directly or indirectly. Hence, as Plaintiffs' Expert Dr. Raymond Hartman has written, "AWP is interpreted by the industry as a measure of the underlying structure of drug

[11] *In re Brand Name Prescription Drugs Antitrust Litigation*, Case No. 94 C 897; MDL No. 997, United States District Court for the Northern District of Illinois.
[12] Laurie P. Cohen and Elyse Tanouye, "Bitter Pill: Drug Makers Set to Pay $600 Million to Settle Lawsuit by Pharmacies – Retailers Object to Practice of Granting Discounts To HMOs but Not Them – Eight Defendants to Fight On", *Wall Street Journal*, 18 January 1996, p. A1.
[13] A branded drug can be either a patent-protected single source drug, an innovator branded drug that has lost patent protection and faces generic competition, or in some cases, a patent-protected drug sold under distinct brand names, or in even rarer cases, a "branded generic" that is a multisource drug promoted by its brand rather than chemical name. Multisource drugs include both brands that have lost patent protection and generic drugs.
[14] Although "AWP: Ain't What's Paid" was prominently displayed in the 1996 Barron's article (Bill Alpert, "Hooked on Drugs: Why do insurers pay such outrageous prices for pharmaceuticals?", *Barrons*, June 10, 1996, 3 pp), as I note below, this association with AWP has an earlier history.

prices,"[15] and "The AWP, or its formulaic equivalent the WAC (wholesale acquisition cost), is interpreted by industry as the signal for the underlying structure of list and transaction prices for almost all drugs."[16]

17. Given the widespread knowledge that AWP has long overstated actual transactions prices among manufacturers, providers, PBMs and retailers, as I understand it, in this litigation Plaintiffs are alleging that while payors understood that discounts off AWP were pervasive, certain manufacturers have covertly manipulated further the AWP and actual transactions cost structure of drug prices, resulting not just in an inflated AWP, but in an "artificially inflated"[17] or "grossly inflated"[18]AWP, which in turn allegedly damaged certain end-payer classes. These damages depend in large part on the "spread" between AWP and the actual average selling price ("ASP") in the case of manufacturer contracts with PBMs, or between AWP and the actual average acquisition costs ("AAC") in the case of sales by manufacturers to distributors or health care providers.[19] As examples, Plaintiffs call attention to recent guilty pleas and settlements involving physician-administered (not self-administered) drugs such as Lupron (an anti-cancer agent, marketed by Abbott Laboratories, Takeda Chemical Industries, Ltd., and TAP Pharmaceutical Products, Inc.) and Zoladex (a slightly different anti-cancer agent, marketed by AstraZeneca Pharmaceuticals LP)[20]. I note that these guilty pleas involved defendants' actions

[15] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, p. 1.
[16] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, p. 3.
[17] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, p. 6; *Plaintiffs' Memorandum In Opposition to Defendants' Motion to Strike the Hartman Declaration*, December 17, 2004, p. 10.
[18] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, p. 72.
[19] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, p. 6. As I note later, this is but one definition of "spread".
[20] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, p. 6, fn. 18; also p. 8, and p. 13 fn. 32.

of providing free samples to physicians, and encouraging physicians to bill Medicare at the published AWP.[21]

18. In assessing whether the proposed end-payer classes were damaged, Plaintiffs' Expert Dr. Hartman proposes first to compute the spreads between AWP and ASP "for drugs unaffected by the scheme and fraud", and then use these as "yardsticks" in comparison with spreads observed "for the drugs subject to this litigation". In cases where he determines the latter spreads are larger than the former, Dr. Hartman proposes to employ his yardsticks along with mathematical and algebraic formulae "to determine the spread that would have been used for the affected drugs but-for the wrongful scheme", thereby determining "the overall class-wide injury and damage for each drug".[22]

19. Because there are numerous types of transactions among different parties in the drug distribution system (among manufacturers, wholesalers, pharmacies, pharmaceutical benefit managers ("PBMs), and third party payors (including health plans, insurers, and employers), there are many alternative concepts of "spreads". I will try to distinguish these as I proceed in this report. For example, at the Plaintiffs' tutorial before Judge Saris on December 6, 2004,

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[21] In the United States District Court for the District of Massachusetts, Eastern Division, *United States of America v. TAP Pharmaceutical Products, Inc., Criminal Action No. 01-CR-10354-WGY, Sentencing Memorandum of the United States,* the civil and criminal resolution was limited to TAP's violation of the Prescription Drug Marketing Act, for losses suffered by Medicare and Medicaid as a result of TAP's fraudulent drug pricing schemes and sales and marketing misconduct, and for losses suffered by Medicaid for TAP's failure to provide "best price" for Lupron. There is no explicit charge of inflating or artificially inflating AWP, although TAP's ability to change AWP at any time is acknowledged. In United States District Court, District of Massachusetts, MDL No. 1430, Master File No. 01-CV-10861-RGS*, In Re: Lupron Marketing and Sales Practices Litigation, Memorandum and Order on Defendants' Motion to Dismiss Corrected Consolidated Amended Class Action Complaint and Second Amended Consolidated Complaint*, Judges Stearns cites Plaintiffs' allegation that defendants' (including TAP) conspired "to artificially inflate the price of the drug Lupron" (p. 1). The Judge later states that "…defendants trumpeted a lie by publishing the inflated AWPs, knowing (and intending) them to be used as instruments of fraud" (p. 18), and comments that "there is a difference between a sticker price and a sucker price" (fn. 19, p. 20). In the case of Zoladex, press releases on AstraZeneca's guilty plea to criminal charges of fraud in the marketing and pricing of Zoladex variously refer to "deliberately inflating" the reported AWP (see http://www.ago.state.ma.us/sp.cfm?pageid=986&id=1050, p. 1, accessed 12/31/04), and "improperly setting and reporting its price" (see http://www.astrazeneca.com/pressrelease/500.aspx , p. 1, accessed 12/31/04).

[22] *Plaintiffs' Memorandum In Opposition to Defendants' Motion to Strike the Hartman Declaration*, December 17, 2004, p. 3.

Professor Meredith Rosenthal discussed another concept and measure of "spread" that for a PBM referred instead to what the PBM charged the payor/insurer (e.g., AWP – f% + administrative fees) minus what the PBM reimbursed the pharmacy (e.g., AWP – g% + dispensing fee + administrative fee), in which case the PBM "spread" equaled g% - f% + differential fees.[23] Professor Rosenthal also appears to assert that for the self-administered drug classes, each class member must have a contractual relationship with a PBM.[24]

III. THE ORIGINS, EVOLUTION AND PERSISTENCE OF AWP AND "SPREAD"

A. Brand Name/Single Source Self-Administered Drugs

20. To understand today's interactions among drug manufacturers, wholesalers, retailers and PBMs, it is informative to consider briefly the history of how AWP, and differences between AWP and WAC, came into being, along with the important role of information and communications technology in affecting distribution costs and industry structure. Unfortunately, much of this history is anecdotal and oral, known by the legions of economists, industry consultants and attorneys involved in the now legendary Brand Name Drug Litigation involving branded (typically patent-protected) self-administered medications (orals, topicals, inhalants, self-injectables and other miscellaneous products). Interestingly, in the context of this litigation a hint of this history is given in the deposition of AstraZeneca's John R. Freeberry, on which I will comment further below.[25]

21. To the best of my knowledge, the first widely circulated written discussion of the AWP history is that by Professor E. M. (Mick) Kolassa, who in 1997 authored a textbook, *Elements of*

[23] *Written Tutorial of Meredith Rosenthal*, Ph.D. presented before Judge Patti B. Saris, United States District Court for the District of Massachusetts, December 6, 2004, p. 16.
[24] *Written Tutorial of Meredith Rosenthal*, Ph.D., supra, p. 12.
[25] Deposition of John Richard Freeberry, May 20, 2004, pp. 168-172. These pages are reproduced as Exhibit 2 in the *Declaration of Steve W. Berman in Support of Plaintiffs' Reply to AstraZeneca Pharmaceuticals LP's Individual Memorandum in Opposition to Class Certification*, December 17, 2004.

Pharmaceutical Pricing.[26] Substantial portions of the material in that text overlap, however, with paragraphs in an earlier 1994 peer-reviewed article,[27] as well as with presentational material prepared for previous marketing consulting/research seminars conducted by Professor Kolassa.[28] Kolassa [1997] begins by defining AWP as follows:

> "Neither an average price nor a price charged by wholesalers, this figure is a vestige of earlier times. Few, if any, wholesalers even consider AWP today when pricing their prescription products. It is, however, commonly used by retailers and others who dispense medications as the basis for many pricing decisions. Due to its availability from many sources, the AWP is often used as a surrogate for actual prices when studying prescription price trends".[29]

22. In Kolassa [1994a], the original *raison d'être* for AWP and for the now infamous common 20%-25% "spreads" between wholesalers' acquisition and retail pharmacy acquisition costs of branded self-administered drugs is recounted. Recall that during the 1980s, following the pioneering practices of WalMart and other "superbox" retailers, implementation of information and communications technological developments significantly impacted the rationalizing of wholesaler-retailer distribution logistics, the monitoring of transactions in real time, and the management of inventory, reducing costs and in the process leading to the demise of many small retail and wholesale firms. These phenomena also occurred in the context of pharmaceuticals.[30] Despite its length, the following quote from Kolassa [1994a] is illuminating:

> "The AWP, the most common figure used for drug price comparisons, is a vestige of a drug distribution system that disappeared in the early 1980s. Prior to that

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[26] E. M. (Mick) Kolassa, *Elements of Pharmaceutical Pricing*, Binghamton, NY: The Pharmaceutical Products Press, 1997.
[27] Mick Kolassa, "Guidance for Clinicians in Discerning and Comparing the Price of Pharmaceutical Agents", *Journal of Pain and Symptom Management*, 9(4), May 1994: pp. 235-243. Hereafter I denote this reference as Kolassa [1994a].
[28] See, for example, *Elements of Pharmaceutical Pricing: A two-day marketing research seminar*, Radisson Hotel & Suites, Fairfield, NJ, August 9-10, 1994. Hereafter I denote this reference as Kolassa [1994b].
[29] Kolassa [1997], *supra*, p. 30.
[30] For another discussion on the impacts of information and communications technology on wholesale-retail interactions in the pharmaceutical industry, see "Computers as Agents of Change" (pp. 61-65) and "Retailing Reorganized" (pp. 65-67) in John T. Fay, Jr., "The Wholesaler", ch. 12 in Mickey C. Smith, ed., *Principles of Pharmaceutical Marketing*, Third Edition, Philadelphia: Lea & Febiger, 1983.

time, there were several hundred small, independent drug wholesalers, each operating regionally. Due to the inefficiencies of such a fragmented system, the operating costs were quite high. The average markup above cost by these wholesalers to their retail customers, primarily pharmacies, was 20% to 25%, depending on manufacturer. The manufacturer differences were due to the fact that, while most pharmaceutical manufacturers used a wholesaler-only method of distribution to the retail class of trade, a significant number of large firms had invested in their own distribution networks and preferred 'direct' sales over the use of wholesalers. By convention, wholesalers added 20% to the price of products from companies following a wholesaler-only policy while adding 25% to the prices of products from those companies who chose to 'compete' with the wholesalers. At that time, virtually all pharmaceutical companies sold products directly to hospitals that did not use wholesalers. As a result, less than one-half of the pharmaceutical products sold in the United States were handled by drug wholesalers in the early 1970s. {Footnote in Kolassa [1994a] omitted.}

In the late 1970s and early 1980s, several wholesale drug companies began to acquire smaller competitors. At that time, a few companies expanded significantly, many becoming national in scope. As a result, there are fewer than 90 separate wholesaler drug companies today, with more consolidations expected in the next few years. The expansion of major firms also concentrated competition. Prior to this consolidation, most wholesalers had little or no competition, so there was little pressure to reduce their markups. The consolidation in the industry resulted in major wholesale companies competing for the same business. The net effect was price competition.

This expansion of major wholesalers led to greater efficiencies as the wholesalers adopted more sophisticated inventory control systems, and to the expansion of services offered to retail and hospital customers. Large wholesalers then used their competitive advantages to gain and keep new customers. The utilization of wholesalers increased substantially during this period, resulting in the wholesalers' handling of over 80% of prescription product sales by 1987. {Footnote in Kolassa [1994a] not reproduced here.}

Additionally, during the 1980s, the prices charged by the manufacturers began to increase. This allowed the wholesalers to practice arbitrage, buying drugs in anticipation of price increases, then selling their inventory at the new, higher prices. These combined forces brought the average wholesale markup today to roughly 2.5%, significantly lower than the markup implied by the published AWP.

Price-reporting services, however, still rely upon the AWP as their primary figure, because many companies publish only that figure (usually called the "suggested price to pharmacy"). A recent move by several manufacturers, however, is to publish only their own list prices, refusing to offer the traditional AWP figure. This has been done, reportedly, because many name-brand drug makers feel the

> AWP unfairly distorts their prices and results in competitive disadvantages. The AWP, although not the cost paid by retailers, still provides the basis for much retail pharmacy pricing, with retailers euphemistically referring to the difference between their actual cost and the AWP as 'earned discount'. This tradition is so ingrained that a retailer that sells a product at AWP, which is 12%-18% above their cost, refers to this price as a 'loss leader'."[31]

Kolassa summarizes this discussion by stating, "Within pharmacy circles, the definition of AWP, it is joked, is 'Ain't What's Paid.'"[32]

23. The evolution of the AWP – WAC "spread" for branded self-administered pharmaceuticals is therefore, as best I can tell, quite understandable, and apparently not the result of any sinister or nefarious conspiracies. Moreover, since AWP was publicly known, it served as a convenient focal point metric for contractually specifying various reimbursements, and for efficiently adjudicating pharmacy transactions electronically.

24. Why this "spread" practice has continued long after its underlying rationale has largely disappeared is a bit puzzling, but is I believe understandable and plausible. Given the AWP – WAC history, retail pharmacies plausibly continued to expect their acquisition costs to be 20-25% below AWP, and thus in their contracts with third party payors and PBMs, retailers generally expected to be reimbursed at 10-15% below AWP. In such a context, one can understand that a single manufacturer marketing a newly FDA approved drug would find it quite challenging if not impossible to successfully set an AWP that was only, say, 2-5% above the WAC, for with that small a differential, retailers would be unable to recover their acquisition costs, unless they renegotiated and rewrote contracts with PBMs and other third party payers (such contracts typically applied a uniform percent discount across all single source branded self-administered drugs, regardless of therapeutic class).[33]

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[31] Kolassa [1994], *supra,* pp. 236-237; much of this material is reproduced in Kolassa [1997], *supra*, pp. 33, 35-36.
[32] Kolassa [1994a], *supra,* p. 237.
[33] The percent figure typically varied, however, depending on whether the drug was a brand or generic.

25. An example may help to clarify this. Suppose that the AWP of Drugs X and Y is a common $100, and that their WAC is a uniform $80 (the AWP in both cases is 25% above the WAC). Suppose further that the pharmacy's acquisition cost for both drugs is equal to WAC, which is a reasonably decent approximation to actual retail pharmacy acquisition costs;[34] hence the pharmacy's actual acquisition cost ("AAC" for the moment) equals $80. Finally, suppose that in its contract with a health plan or PBM, the pharmacy is reimbursed for all branded self-administered drugs at AWP – 15%.[35] This means that for each prescription of Drug X or Drug Y dispensed to a beneficiary of the health plan, the pharmacy is reimbursed at $85 (with an AWP of $100, AWP – 15% is $100 - $15 = $85). Notice that in this example, the pharmacy's gross margin on each prescription is $5 (it is reimbursed $85 by the health plan/PBM, and acquires the drug for $80).

26. Now suppose that for whatever reason, the manufacturer of Drug X wants to bring AWP much closer into alignment with the WAC, and instead of setting an AWP spread of 25% over WAC, it seeks to reduce the premium to 10%. This reduces the AWP for Drug X from $100 to $88 (110% of the $80 WAC price). Now, with reimbursement contracts between health plans/PBMs and retail pharmacies unchanged, the pharmacy will continue to be reimbursed for all branded self-administered drugs at AWP – 15%. Hence, the pharmacy would continue to be reimbursed at $85 per prescription for Drug Y. While the pharmacy would also still be reimbursed for Drug X at 85% of AWP, now, however, the AWP will have fallen from $100 to $88, implying that reimbursement from the health plan/PBM would only be 85% of $88, or $74.80. With an unchanged acquisition cost of $80 for both Drugs X and Y, the pharmacist

[34] See, for example, Congressional Budget Office, *Medicaid's Reimbursements to Pharmacies for Prescription Drugs,* December 2004, p. 8, fn. 12; Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Abt Associates Inc., Cambridge, MA, August 30, 2004, p. 14.
[35] For simplicity, here I ignore dispensing fees and other administrative charges/fees.

would lose on each prescription for Drug X (receiving $74.80 in reimbursement but having an $80 acquisition cost, implying a $5.20 loss on each Drug X prescription). The pharmacy would, however, continue to earn a $5 gross margin on Drug Y. Clearly, the manufacturer of Drug X would find it difficult to sell its drug to the retail pharmacist, due to the lower AWP – WAC spread policy it implemented only for Drug X.

27. Recognizing this problem with retail pharmacies, the manufacturer of Drug X might try to arrange for unique treatment from health plans/PBMs contracting with pharmacies. Specifically, the manufacturer might attempt to have all contracts between all pharmacies and health plans/PBMs rewritten so that, unlike all other branded self-administered drugs reimbursed at AWP – 15%, Drug X would be reimbursed at AWP – 3.5%.. With this new reimbursement formula, the pharmacies' gross margins for Drug X would continue to be about $5 (or very slightly smaller at $4.92), thereby making neutral or roughly equal the reimbursements received by the pharmacy for Drug X and Drug Y.[36] However, precisely because of the efficiency advantages of common contracting terms and common algorithmic formulas in processing pharmacy claims electronically, the health plans/PBMs and pharmacies would likely strongly resist such costly special treatment of Drug X. Even if the manufacturer were a very, very large manufacturer with a large portfolio of branded self-administered drugs, and even if it proposed reducing the spread on all its products, not just Drug X, it is very likely that the proposed policy change would be a failure commercially, and that pharmacies and health plans/PBMs would offer strong resistance.[37]

[36] In this example, for an AWP of $88, AWP – 3.5% is $84.92. With an acquisition cost of $80, the pharmacy gross margin would be $4.92. A manufacturer to pharmacy pricing policy of AWP – 3.40909% would yield an almost perfectly neutral gross margin of $5 for Drug X, identical to that for Drug Y.

[37] I am aware of course that Defendants' reducing the spread between AWP and actual acquisition costs is not the behavior alleged by Plaintiffs in this litigation.

28. In the current litigation, AstraZeneca deponent John R. Freeberry apparently refers to such an experience when in about 1994, the newly formed Astra Merck joint venture had to deal with two different legacies from its parent companies, one involving an AWP 20% greater than WAC, and the other a 25% differential. Astra Merck apparently sought to change the AWP – WAC differential from 25% to 20%, and may have even considered a more dramatic pricing policy change involving publication of an AWP that even more closely approximated average transaction price. According to Freeberry:

> "…the reason we couldn't really do that was because pharmacists are reimbursed on a set contract for all of their brands. That's our understanding of it. So they're reimbursed an AWP minus 10 percent, minus 15 percent.
>
> So if we set our AWP at 2 percent, obviously they would lose money, and they wouldn't use our products. So we have to be consistent with the industry standard in order for the – to be – competitively fair."
>
> Q: "When you're referring to having changed the whole industry, are you referring to anyone other than the retailers and what you've just described with retailer contracts?"
>
> A: "I'm referring to the whole reimbursement process for the pharmacists. All these contracts are based on AWP price to the retailers."[38]

29. These observations suggest the very plausible hypothesis that even though the original rationale supporting the AWP – WAC or AWP – ASP differential for brand name/single source self-administered drugs had largely disappeared by the 1980s, there were no incentives for any one manufacturer to change the system pricing structure, and indeed, the incentives that did exist were perverse in that unilaterally publishing more accurate AWP prices would be unprofitable and therefore unsustainable for any one manufacturer.

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[38] Deposition of John Richard Freeberry, May 20, 2004, pp. 175-176 (quotation); this line of questioning begins earlier, on page 170. These pages are reproduced as Exhibit 2 in the *Declaration of Steve W. Berman in Support of Plaintiffs' Reply to AstraZeneca Pharmaceuticals LP's Individual Memorandum in Opposition to Class Certification*, December 17, 2004.

30. Moreover, even if each company unilaterally decided to participate in a coordinated industry-wide agreement to change AWP/WAC pricing practices, such actions might invite antitrust scrutiny and challenge from the U.S. Department of Justice. Such antitrust concerns apparently occurred in the early 1990s when pharmaceutical manufacturers considered (and then rejected) the idea of mutually pledging to keep brand name drug prices from rising more rapidly than the Consumer Price Index.[39] In the current litigation, I note that in fact related antitrust allegations have been made by Plaintiffs involving participating defendants in the Together Rx Card program.[40]

31. In summary, for brand name/single source self-administered drugs, while the underlying rationale supporting a 20-25% spread between AWP and WAC has long disappeared, manufacturers and retailers appear to be locked in to this practice. In the jargon of economics and game theory, what we observe is a Nash equilibrium in which for all players AWP exceeds ASP and WAC. There is no incentive for any brand name manufacturer of self-administered single-source drugs to align its AWP to a level much closer to WAC.

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[39] Following Merck's 1990 announcement of a voluntary commitment to limit annual prices increases to no more than growth in the overall Consumer Price Index ("CPI"), several other pharmaceutical firms followed suit. In 1993 the Pharmaceutical Manufacturers Association ("PMA") requested a business review by the U.S. Department of Justice of a program it proposed to implement, whereby member companies would commit to limiting annual price increases at rates not to exceed growth in the CPI, subject to independent audit. On October 1, 1993, Assistant U.S. Attorney General Anne Bingaman responded for the Department of Justice, opining that "the Department currently intends to bring suit to challenge the program if PMA and its members go forward with this proposal". Bingaman went on to write that "…the proposed program would violate the antitrust laws. An agreement among independent competitors that interferes with free and open price competition by restraining individual pricing decisions is a per se violation of the Sherman Act. The per se rule has been applied to agreements among competitors that fix or set the prices at which goods or services are sold as well as agreements that set price-related terms but not the specific price at which transactions occur." Online at http://www.usdoj.gov/atr/public/busreview/0772.htm, pp. 1,2.

[40] As I understand it, in the current litigation, the Nationwide End Payor Together Card Class Plaintiffs allege conspiracy and Sherman Act violations when defendants allegedly moved almost simultaneously to a common 25% spread between AWP and WAC for drugs covered by the Together Rx Card. See *Corrected Amended Master Consolidated Class Action Complain Modified Per the Court's Instruction at the November 21, 2003 Hearing with Amgen Amendments,* United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, December 5, 2003, Counts V through X, pp. 280-304.

32. An alternative potential source of change in bringing about more accurate public average prices could have been the federal government. While over the years the federal government has purchased a limited number of drugs in its Medicare Part B program, together with the states it currently pays for a much larger amount of drugs through the states' Medicaid programs. I will return to the federal government's role as possible agent of change in bring published prices closer to actual acquisition prices in sub-section C below.

B. Generic/Multisource Self-Administered Drugs

33. During the 1970s and 1980s when wholesaler-retailer interactions were revolutionizing electronic transactions, generic drugs played a relatively minor role, not only in numbers, but also in dollar sales proportions. While the share of prescriptions of self-administered drugs dispensed generically has increased substantially in the last two decades, their dollar share has remained relatively modest, typically in the range of 10%-20%.

34. According to a 1985 Federal Trade Commission study, in 1980 31% of prescriptions were written for single-source drugs, while 69% were written for multi-source drugs. However, among the 69% written for multi-source drugs, 55% had the brand name written on the prescription, while the remaining 14-15% specified the generic (not brand) name. Almost all prescriptions written with the brand name were dispensed as written (52% of the 55%), and only for a small portion (3% of the 55%) was a generic substituted for the brand.[41] The total proportion of prescriptions dispensed as generics was therefore about 18% (15% written as generic, plus 3% substituted with generic).

35. Since at that time the average retail prescription price of a generic was about 75% of that for a brand ($6.22 vs. $8.22), as a proportion of generic plus retail drug revenues, the generic

[41] Alison Masson and Robert L. Steiner, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws*, Staff Report of the Bureau of Economics, Federal Trade Commission, October 1985, p. 26, Figure 2-1. Washington DC: U. S. Government Printing Office.

dollar share in 1980 was about 14%.[42] Relatively speaking, therefore, in 1980 generics were not that important at the retail level, although even then the average retail gross margin was larger than that for brands, not only proportionally, but even in absolute terms.[43]

36. Several years later, at the time Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act), the generic share of prescription units was essentially unchanged at 18.6%. In the years that followed, two offsetting trends occurred that significantly affected retail pharmacies and the sources of their profitability.

37. First, the growing effects of states' mandatory generic substitution laws, along with much greater entry by generic manufacturers facilitated in part by the Hatch-Waxman Act, resulted in the proportion of total prescriptions dispensed as generics increasing sharply – from 18.6% in 1984 to 32.0% in 1989, 41.6% in 1994, and 47.1% in 1999.[44]

38. Second, the gap in average retail price per prescription between brand and generic drugs increased substantially for retail pharmacies, implying that even though the proportion of prescriptions dispensed as generics increased sharply after 1984, the proportion of retail pharmacy prescription drug revenues attributable to generics did not rise by nearly as much. For example, while in 1980 the relative average brand price was about 32% larger than that for a generic prescription ($8.22 vs. $6.22), by 1994 this gap increased to more than 200% ($53.80 vs.

[42] In Masson and Steiner, *supra*, Table 3-1, p. 36, the average retail price of a brand prescription in 1980 is reported as $8.22, while that for a generic is $6.22. Multiplying these per prescription prices by their sales proportions implies that of the $7.8 billion total pharmacy revenues, about $1.12 billion, or 14.2%, were attributable to generics.
[43] Masson and Steiner, *supra*, Table 3-1, p. 36, report that the absolute gross margins per prescription were $3.35 (brands) and $3.57 (generics), with invoice costs being $4.86 and $2.65, respectively. As a proportion of the average retail price, therefore, the brand gross margin was about 41%, while for generics at 57% it was larger.
[44] Pharmaceutical Research and Manufacturers of America, *2000 Industry Profile*, PhRMA, Washington DC, 2000, Figure 5-7, p. 69.

$17.40).[45] Between 1980 and 1994, the average retail single source brand prescription price increased by about a factor of six, while that for a generic increased by only slightly less than a factor of three. As a proportion of retail pharmacy sales, the generic comprised 17.3% of revenues, only slightly larger than the 14.2% in 1980.[46]

39. Viewed from the vantage of third party payors, while the generic share of total prescription drug expenditures continued to be relatively small at 14-17%, from the point of view of retail pharmacies the proportion of gross profit margins attributable to generics was much larger. In the same year (1994), for example, IMS Health reported that as a proportion of pharmacies' total prescription drug acquisition costs, generics accounted for but 10%, while brands (and so-called branded generics) comprised the remaining 90%.[47] For retailers, therefore, generics have provided a relatively large source of profits – only 10% of costs, but 17% of revenues in 1994.

40. A just recently released study conducted by the Congressional Budget Office provides evidence of the continuing profitability to pharmacies of dispensing generic drugs. In 1997, 2000 and 2002, for example, while pharmacies' average acquisition costs of generic drugs were $4.30, $4.20 and $6.00, respectively, the amounts pharmacies were on average reimbursed by Medicaid for these generic drugs were $12.00, $16.10 and $19.90, implying absolute gross margins of $7.70, $12.00 and $13.80.[48] The CBO study went on to note that pharmacies' generic

[45] The gap between average brand and average generic prescription price from retail continues to grow. In 2002, for example, the average prescription retail price to consumer was $81.68 for a brand and $25.13 for a generic, a 225% difference. See Healthcare Distribution Management Association, *2003 HDMA Industry Profile and Healthcare Factbook*, Table 205, p. 129.
[46] U. S. Congress, Congressional Budget Office, *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998. Available at http://www.cbo.gov/showdoc.cfm?index=655&sequence=0&from=1 .
[47] *The U.S. Pharmaceutical Market Year-in-Review 1995*, IMS International, Powerpoint presentation, p. 8, slide 23.
[48] U.S. Congressional Budget Office, Medicaid's Reimbursement to Pharmacies for Prescription Drugs, December 2004, Table 2, p. 4.

drug absolute gross margins had grown particularly rapidly for new multisource drugs, i.e. for drugs with initial generic entry after 1997.

41. The essential reason that brands and generics have such differing gross profitability profiles for retail pharmacies stems from retailers' differential buying power in these two segments. For any given prescription drug available from more than one generic manufacturer, the retail pharmacy buyer (particularly when organized into chains or other large buying groups) can stimulate price competition among the generic manufacturers. This occurs since the retail pharmacist can credibly threaten to substitute between any of the FDA-certified bioequivalent generic versions of a drug, choosing the particular version having the most favorable price comparison, thereby stimulating price competition among generic manufacturers. Moreover, commercial reimbursement from health plans/PBMs to pharmacies is typically the same, regardless of the generic manufacturer from whom the drug is purchased.

42. By contrast, in most cases the retail pharmacy cannot freely substitute between different patent-protected single source brands, unless explicit permission is first obtained from the prescribing physician. This inability to stimulate price competition among single-source brands means that when negotiating with branded manufacturer, the pharmacies have little bargaining power, and are essentially price takers.

43. In terms of the historic relationship between AWP and pharmacies' acquisition costs, and between AWP and pharmacies' reimbursement from third party payors, the picture for generics is considerably more complex and diverse than that for brands. Kolassa [1994a] paints a slightly different and potentially less benign picture for generic/multisource self-administered drugs:

> "This use of the AWP is even more pronounced with generic drugs. Many generic companies have taken advantage of this use of AWP by inflating their

> published AWPs substantially. For instance, in 1989 Geneva Generics increased some AWPs by as much as 1000% while decreasing their selling prices."[49]

44. After providing several examples in a table involving two nonsteroidal anti-inflammatory drugs both available in brand name and generic versions, Kolassa [1994a] characterizes the generic AWP phenomenon in a way strikingly similar to allegations made in the current litigation by Plaintiffs: [50]

> "This tactic, then, allows retailers to acquire a drug at a low cost, less than $5.00 per hundred, yet rely on a published AWP as high as $15.00 or more for their own pricing. It is not uncommon that the $25.00 retail price for a generic drug renders a gross profit well above $20.00 for the retailer."[51]

In his very similar 1997 textbook description of this phenomenon, Kolassa adds "It is also common for the AWP of a generic product to remain stable while the actual selling price declines."[52]

45. After providing a table documenting percentage differences between ex-factory prices and AWP ranging from 20% to 1,168%, Professor Kolassa concludes as follows, noting the heterogeneity in the pricing policies undertaken by generic manufacturers:

> "It is obvious that AWP is not an accurate measure of the prices manufacturers charge. It must also be noted that not all generic products will be priced similarly. Some, in fact, use the more traditional method of a 20% markup to reach an AWP. This can be a handicap for generic companies choosing this method because retailers often use the AWP as the starting point for many pricing decisions and an artificially high AWP provides the retailer with greater profits."[53]

46. The relationship between AWP, WAC and actual acquisition prices for generic self-administered drugs is considerably more complex, therefore, than that for single source branded

[49] Kolassa [1994a], *supra*, p. 237.
[50] Indeed, in the paragraphs that follow, the quoted portions are virtually identical to unreferenced statements produced in *Plaintiffs' Amended Motion for Class Certification*, United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, December 17, 2004; see, for example, pp. 46-47.
[51] Kolassa [1994a], *supra*, p. 237.
[52] Kolassa [1997], *supra*, p. 37.
[53] Kolassa [1997], *supra*, pp. 37-38.

drugs. This complexity and variability has been known for quite some time. In 1992, for example, Henry Grabowski and John M. Vernon published a peer-reviewed article that examined generic entry patterns and pricing following 1984 passage of the Hatch-Waxman Act.[54] The measure of price used by Grabowski-Vernon was the average cost per unit paid by drugstores and hospitals for the most frequently consumed dosage size of each product.[55] Regarding generic price variability, Grabowski and Vernon report that:

> "One indication of the significant variability in generic prices is the fact that, in half of the eighteen generic products, the maximum price observed is over 50 percent greater than the minimum price, as measured one year after initial entry."[56]

For five of the eighteen products, the maximum price was in fact more than twice the minimum price.[57]

47. The Grabowski-Vernon study examined generic pricing patterns in the 1980s and early 1990s. The complexity and volatility of generic pricing persists. Plaintiffs' Expert Dr. Stephen Schondelmeyer reports that even in the more current context, the relationships among AWP, WAC and actual acquisition costs vary between single source brands, multisource brands, and multisource generics, and by class of trade.[58] In a recently jointly authored research report with Marian V. Wrobel, for example, he makes the following set of statements that highlight some of the differences between brand and generic self-administered drugs:

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[54] Henry G. Grabowski and John M. Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act", *Journal of Law and Economics*, Vol. 35, October 1992, pp. 331-350.
[55] Grabowski and Vernon [1992], *supra*, p. 335.
[56] Grabowski and Vernon [1992], *supra*, p. 345.
[57] Grabowski and Vernon, *supra*, Table A2, p. 349.
[58] Ten classes of trade identified by Schondelmeyer and Wrobel are: chain pharmacy, mass merchant pharmacy, food & drug pharmacy, independent pharmacy, mail order pharmacy, health plan pharmacy, clinic & doctors' office; long term care pharmacy, hospital, and government facilities & other. See Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Abt Associates, Inc., Cambridge, MA, Prepared for Centers for Medicare and Medicaid Services, Contract #500-00-0049, August 30, 2004, p. 12.

"Most experts agree that AWP, or even the typical discounts to AWP, exceed actual acquisition costs for both pharmacies and physicians. This is particularly true for generic drugs."[59]

"The terms for describing drug prices have changed over the past four decades. New terms have emerged and old terms have developed new meanings. Careful definition of drug pricing terms is important to assure consistency and confidence in the prices reported and to assure propriety and accuracy when establishing payment and public policy."[60]

"In the past decade, WAC was a term that typically included adjustments for discounts, rebates, purchasing allowances, or other forms of economic consideration. {Footnote Not Repeated}. More recently, WAC has come to mean a list price before any form of price adjustment. WAC is closer to wholesaler's actual acquisition cost than is AWP. *However, due to different levels of discounts across drug products and specific classes of trade, the WAC does not generally have a reliable relationship to the actual acquisition cost. Within a specific class of trade, WAC may have a consistent relationship with the actual acquisition cost for single source brand name (patented and exclusivity protected brands) drug products, but not for innovator multiple source (off-patent brands) or non-innovator multiple source (generic) drug products."*[61]

"A larger share of generic drugs, than of brand-name drugs, is sold direct from the manufacturer. *Because of different levels of discounts, the DP does not have a reliable relationship to the actual acquisition cost, in general, or for specific classes of trade."*[62]

"When two or more generics enter the marketplace they typically compete on price with each other even though the brand name product usually does not compete on price. The first generic will typically enter the market at a list price (both AWP and WAC, if a WAC is reported) that is 10 to 30 percent below the originator brand price. Often the price competition among generic versions of a drug product will be reflected by one or two decreases in list prices (AWP and WAC) in the first six to twelve months after generic entry, but after that time it is rare to see generic list prices change and at some point in time the generic list prices for some drugs may even begin to rise again."[63,64]

"The relationship between list prices (AWP and WAC) is much less predictable for generic drugs than it is for brand name drugs. Some generic drug products will have AWPs that are the typical 20 to 25% above the WAC, but it is not unusual to see generic

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[59] Schondelmeyer and Wrobel [2004], *supra,* p. 7.
[60] Schondelmeyer and Wrobel [2004], *supra*, p. 13.
[61] Schondelmeyer and Wrobel [2004], *supra,* p. 14. Italics not in original..
[62] Schondelmeyer and Wrobel [2004], *supra,* p. 15. Italics not in original. DP (direct price) is defined by Schondelmeyer and Wrobel on the same page as "a *list price* used for *invoices between drug manufacturers and pharmacies or providers…*" (italics in original text).
[63] Schondelmeyer and Wrobel [2004], *supra*, p. 17.
[64] Defendant's Expert Steven J. Young also notes that some generic manufacturers do not even have a WAC. See *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, October 25, 2004, p. 64, Paragraph #188.

> *drug products with an AWP that is 50 to 100 percent, or more, above the WAC. Even more volatile is the relationship between the list prices (AWP or WAC) and actual acquisition costs for generics.* Generic firms often discount their actual net price to the pharmacy to compete with other generics, but they do not always reflect these discounts to lower AWP or WAC list prices. *Generic prices are also relatively volatile, because the market for generic drugs is effectively a commodity market*. Thus, AWP-based payment policy is much less accurate for these drugs than it is for the branded drugs."[65]

48. In terms of the final recommendations Schondelmeyer and Wrobel make to CMS regarding how both Medicaid and Medicare Part B might most reliably estimate actual acquisition costs of the drugs it reimburses providers, the first sentence in their Section "Recommendations and Directions for Further Work" is remarkably straightforward: "There is no simple method of estimating acquisition costs."[66]

49. One other issue distinguishing reimbursement for brands from generics regards dispensing fees. Recall that pharmacies are typically reimbursed by health plans/insurers/PBMs for drugs they dispense on the basis of a relatively simple formula, such as AWP – x% plus dispensing fee plus (occasionally) administrative fees.

50. A commonly held view is that dispensing fees received by pharmacies have tended to be lower than their actual dispensing costs, but that ingredient cost reimbursement has generally exceeded actual pharmacy acquisition costs, thereby offsetting the underrecovery of actual dispensing costs.

51. Reporting on themes emerging from an Expert Panel Meeting for the Medicaid and Medicare Drug Pricing Project held in January 2004, for example, Schondelmeyer and Wrobel report that in terms of Medicaid, there was "agreement that dispensing fees are lower than actual dispensing costs and that drug payment generally exceeds actual acquisition costs", and that "The spread in drug payment compensates for the low dispensing fees". Indeed, Schondelmeyer

[65] Schondelmeyer and Wrobel [2004], *supra,* p. 18. Italics not in original.
[66] Schondelmeyer and Wrobel [2004], *supra*, p. 28.

and Wrobel apparently quote one expert verbatim, who stated "If it weren't for spread, pharmacies would be out of business."[67]

52. In the context of generic drugs, one widely understood reason third party payors have long been willing to allow pharmacies to enjoy a considerable "spread" on their generic drugs is that whenever a generic version of a drug is dispensed instead of its brand version, the third party payor typically saves a substantial mount of money (recall the earlier discussion on average brand prescription prices being considerably less than average generic prescription prices). Given that it enjoys these large savings, the third party payor is less likely to quibble over whether the pharmacy is pocketing a larger margin for generics than for brands. Recall also that from the vantage of third party payors, the generic share of total prescription costs for self-administered drugs is rather small, typically between 10% - 20%.

53. Defendant's Expert Robert P. Navarro describes his own experiences at the Physician Health Plan of Minnesota ("PHPM") and United Health Care ("UHC") in incenting pharmacies to dispense generically as follows:

> "I have found from my own experience that, in general, increasing generic dispensing has the potential to be one of the most important cost-containment strategies. At PHPM, we attempted to have approximately 50% or more of members' prescriptions dispensed generically. PBMs adopt such programs to encourage pharmacies to substitute generic for brand drugs, where therapeutically appropriate, and in some cases offer a guaranteed substitution rate. (Footnote Not Reproduced}. For example, Caremark has a performance program that rewards pharmacies for achieving certain levels of generic dispensing. {Footnote Not Reproduced}. At UHC, we also used pharmacist incentives (for example, paying a slightly higher dispensing fee for generics) to increase our generic dispensing rate for plans which had lower use of generic drugs."[68]

[67] Schondelmeyer and Wrobel [2004], *supra*, Appendix B, p. B-2.
[68] *Declaration of Robert P. Navarro in Opposition to the Plaintiffs' Motion for Class Certification,* supra, p. 18, Paragraph #36.

54. A 2001 survey covering 468 employers and 15.5 million beneficiaries, conducted by the Pharmacy Benefit Management Institute and supported by the National Business Coalition on Health and the Employers' Managed Health Care Association, documents the extent to which plans employ differential brand-generic dispensing fees to incent pharmacies to dispense generic drugs more intensively:

> "Some employers deliberately pay a higher dispensing fee for generic drugs than for brand drugs as a way to encourage pharmacies to dispense more generics when possible. Approximately 32% of respondents pay a higher dispensing fee for generics. Generally, the generic dispensing fee is higher by $0.50 although some are as much as $1.00 higher."[69]

Since actual pharmacy dispensing costs are unlikely to differ materially between brands and generics, this differential generic-brand dispensing fee policy essentially amounts to a policy of third party payors deliberately allowing and indeed encouraging pharmacies' margins (inclusive of dispensing fee) to be larger for generics than they would otherwise be, and other things equal, to be larger for generics than for brands. In this sense, then, for generic drugs the dispensing fee and ingredient reimbursement are bundled together in ways that attempt to benefit both the third party payor and the pharmacy.[70]

55. A final issue distinguishing brand from generic self-administered drugs involves the formulae and contractual terms that are employed among health plans/insurers/employers, PBMs and pharmacies. Although almost all single source brand drugs are contractually reimbursed using AWP, generic/multisource drugs are more commonly reimbursed by commercial payors on the basis of what is called MAC (maximum allowable cost), or less frequently, MRA (maximum reimbursable amount).

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[69] *Takeda and Lilly Prescription Drug Benefit Cost and Plan Design Survey Report, 2001 Edition*, Tempe, AZ, The Pharmacy Benefit Management Institute, Inc., p. 25. Accessible via email at pbmi@pbmi.com.

[70] This point is also made by Defendants' Expert Steven J. Young. See *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification* [2004], supra, p. 66, Paragraph #194; also see pp. 82-85, Paragraph # 231 – 237.

56. For example, Plaintiff's Expert Dr. Raymond Hartman reports that based on an analysis of 1999-2004 submitted claims to Harvard Pilgrim Health Care, while 98% of all branded drugs in what he calls "Set C" were reimbursed with reference to AWP, for the generic drug reimbursement claims only 37% reimbursed with reference to AWP, while 54% reimbursed with reference to a MAC definition.[71] Dr. Hartman notes that among those generic claims referencing AWP, a substantial portion "are composed of recently-launched generics, since the first several generics launched for any drug explicitly reference AWP."[72] This suggests that for Harvard Pilgrim Health Care, one should expect variability over time in the proportion of generic claims referencing AWP, with the proportion being larger shortly after important, frequently prescribed drugs lose patent expiration and generic entry takes place.

57. I note in passing that Dr. Hartman reports results from other insurers' claims data (University of Pittsburgh Medical Center – 1998 to 2004, and the Carpenters and Joiners Welfare Funds – 2001 to 2004) in which for apparently generic self-administered drugs, the proportion of claims referencing AWP varies considerably across time, insurer, and drug.[73] Based on this preliminary analysis, Dr. Hartman concludes that for generic drugs, "the majority of claims reference MAC."[74] For the same three drugs examined by Dr. Hartman, Defendant's Expert Steven J. Young reports that for Cigna RX, the proportion of new paid claims referencing WAC

[71] *Rebuttal Declaration of Dr. Raymond Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, pp. 27-28 and Attachment B.2.a.
[72] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification* [2004], supra, p. 28.
[73] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification* [2004], supra, pp. 28-30, Attachments B-2b and B-2c.
[74] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification* [2004], supra, p. 30.

is relatively uniform and high: albuterol 88.61% MAC, 4.14% AWP; griseofulvin 89.31% MAC, 1.54% AWP; and theophyline 86.10% MAC, 7.83% AWP.[75]

58. There is considerable documentation and discussion in this litigation concerning the relationship between AWP and MAC for multisource self-administered drugs reimbursed commercially. I shall not reference that extensive literature here. I do, however, want to stress two points. First, while some commercial payors apparently have over the years utilized MAC schedules taken from the Federal Upper Limits schedule published by CMS for Medicaid or from state-specific MAC schedules (these public sector MACs will be discussed further in the following sub-section of this report), a substantial portion of commercial payors have developed their own MAC lists and schedules. Second, commercial MAC lists and schedules are proprietary, and how they are constructed is proprietary information, about which little is publicly known.

59. For example, according to Defendant's Expert Steven J. Young:

> "PBMs and Health Plans consider their MAC lists to be highly confidential trade secrets. {Footnote Not Reproduced}. Most utilize proprietary methodologies for determining the MACs listed. In fact, many Payors agree to reimburse for generics at their PBM's MACs without knowing how those amounts were calculated. (Exhibits 17a and 17b)."[76]

Defendant's Expert Robert P. Navarro concurs, stating that "Many PBMs and health plans create their own MAC lists. Each uses different and typically proprietary methodologies."[77]

60. Plaintiff's Expert Dr. Raymond Hartman also notes that "Private TPPs and PBMs rely upon MAC rather than FUL", and that "Pharmacy Benefit Managers usually create their own MAC lists" (adding a footnote referencing an Express Script pro forma PBM contract that

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[75] *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, October 25, 2004, Exhibit 17d.
[76] *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification* [2004], supra, p. 66, Paragraph #193. Young discusses this further on pp. 66-67, Paragraph #s 194-198.
[77] *Declaration of Robert P. Navarro in Opposition to the Plaintiffs' Motion for Class Certification*, supra, p. 27, Paragraph # 52. Navarro's discussion of commercial MACs is found on pp. 26-29, Paragraph #s 50-56.

provides certain details concerning its definition of MAC). Regarding TPPs (third party payors), Dr. Hartman states, "However, how TPPs actually define MAC and the extent to which the TPPs strictly enforce MAC are unknown."[78]

C. AWP Discounts Attained by Government and Commercial Purchasers

61. In the US, the vast majority of drug prescriptions are paid for by private insurance or consumers' out of pocket payments; in 1998, these two non-government sources accounted for 79.3% of US drug spending. Nonetheless, through its various programs (e.g., Veterans' Administration, TriCare, Medicare, and especially Medicaid), the federal government has become a large volume purchaser; in 1998, Medicaid alone accounted for 17.1% of US drug spending. [79]

62. Over the years, the Office of Inspector General ("OIG") at the Department of Health and Human Services has conducted investigations and publicly issued a substantial number of reports comparing, among others: (i) Medicare and Medicaid reimbursement rates; (ii) Medicare/Medicaid reimbursement rates with prices paid by the Veterans' Administration; and (iii) Medicare/Medicaid reimbursement rates with commercial pharmacies' and providers' acquisition costs. The series of reports has covered physician- and other provider-administered drugs (chemotherapies, inhalation therapies, end stage renal disease drugs) covered through Medicare Part B benefits, as well as various self-administered drugs reimbursed by Medicaid. I summarize a sample of these reports in Attachment B. Other summaries are found in a National

[78] *Declaration of Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification* [2004], supra, Attachment D, p. 13.
[79] U.S. Department of Health & Human Services, *Report to the President: Prescription Drug Coverage, Spending, Utilization, and Prices*, Washington DC, April 2000, Table 2-30, p. 89.

Health Policy Forum Issue Brief,[80] and in documents submitted by Plaintiffs' Expert Dr. Raymond S. Hartman,[81] and by Defendants' Expert Steven J. Young.[82]

63. Even though legislative and implementation guidelines mandated that Medicare reimburse based on the lesser of an estimated acquisition cost ("EAC"), "Usual & Customary" charges or some other "reasonable charge", for a variety of reasons the *de facto* benchmark for Medicare Part B reimbursement was 100% of AWP up until 1998, and then 95% of AWP until 2003.[83] A common finding from the OIG reports is that Medicare reimbursed at higher average prices than did Medicaid, and that the Medicaid reimbursement was less than AWP (often between 10% - 20% less for brands, and even larger reductions from AWP for generics). Medicare also typically paid higher average prices than did the Veterans' Administration, or chain and drug stores, each of which paid prices less than AWP.

64. A common feature of these OIG reports is that oftentimes they contained specific recommendations regarding alternative practices Medicare should consider employing, instead of continuing AWP-based reimbursement policies; in a number of cases, the report contains written responses to these recommendations from the Health Care Financing Administration ("HCFA", the predecessor agency to the Centers for Medicare and Medicaid Services, "CMS") or CMS.[84]

65. While it is not entirely clear why it has taken so very long for CMS to switch from AWP-based to an actual selling price (ASP)-based reimbursement, what is clear is that through

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[80] Dawn M. Gencarelli, "Average Wholesale Price: Is There a More Appropriate Pricing Mechanism?", National Health Policy Forum Issue Brief, No. 775/June 7, 2002, Washington DC: The George Washington University.
[81] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, Attachment D, pp. 2-9.
[82] *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, In Re Pharmaceutical Industry Average Wholesale Price Litigation, MDL No. 1456, Relates to 01-CV-12257-PBS and 01-CV-339, Judge Patti B. Saris, pp. 54-63, Exhibits 7 and 16a.
[83] For further details and an historical discussion, see Medicare Payment Advisory Commission, *Report to the Congress: Variation and Innovation in Medicare*, ch. 9, "Medicare payments for outpatient drugs under Part B", June 2003.
[84] See, for example, Department of Health and Human Services, Office of Inspector General, *Medicaid Pharmacy – Additional Analysis of the Actual Acquisition Cost of Prescription Drug Products*, A-06-02-00041, September 2002.

these published reports and inter-agency public information exchanges, the fact that pharmacies' and providers' acquisition costs were typically less than AWP has long been made very visible and public. It has not been a secret, at least to active observers and health care industry participants.

66. Other government-sponsored studies and reports have also documented substantial discounts off the published AWP. For example, referring to a 1993 report issued by the General Accounting Office,[85] in 1996 the Congressional Budget Office noted that even private buyers obtained substantial discounts:

> "A recent General Accounting Office (GAO) survey found that four HMOs received an average discount off the published list price of 32 percent in 1990 and 34 percent in 1991 on their top 100 outpatient drugs."[86]

The Congressional Budget Office then elaborated on the extent to which AWP overstated actual acquisition costs, as follows:

> "The average wholesale price (AWP) is the published (list) price that manufacturers suggest wholesalers charge their customers. Wholesalers usually charge pharmacists a price that is lower than the AWP, which is the price that is most widely available in published form. In contrast, the average manufacturer price (AMP), used to calculated the Medicaid rebate, is not public information. The AMP is lower than the AWP since it is the average price paid by wholesalers. The Congressional Budget Office (CBO) has examined the relationship between the AMP and AWP to determine the equivalent discount off the AWP that a private purchaser must obtain before the Medicaid best-price provision applies.
>
> CBO examined the relationship between the AWP and AMP for 224 drug products that were the top-selling Medicaid drugs in 1993 (based on data collected by the Health Care Financing Administration for the Medicaid rebate program and the AWPs reported in *Redbook*). For that sample, the AMP averaged 80 percent of the AWP. Therefore, wholesalers paid on average 80 percent of the list price for those drugs. For 84 percent of the 224 drug products examined, the AMP fell between 75 percent and 85 percent of the

[85] General Accounting Office, *Medicaid: Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions*, GAO/HRD-93-43, January 1993.
[86] Congressional Budget Office, *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*, Washington DC: CBO Papers, January 1996, p. 19.

> AWP. Given that the AMP is equal to 80 percent of the AWP on average, a discount of 32 percent off the AWP equals a discount of 15 percent off the AMP on average. [87]

67. The Department of Health and Human Services ("DHHS") has also highlighted the discrepancy between AWP and pharmacies' acquisition costs in its highly publicized Report to the President in April 2000. Here the DHHS explicitly stated:

> "A price that is commonly cited in the industry is the 'average wholesale price', or AWP. Despite what this name would suggest, the AWP is not the average of the amounts actually paid by retail pharmacies to wholesalers for a particular drug. Instead it is a published wholesale price or 'list price' suggested by the manufacturer of the drug. A wholesaler may sell specific drugs to all pharmacies at prices below the AWP, or may grant a general discount to certain pharmacies. Thus, although the AWP is often used by pharmacies as a cost basis for pricing purposes, it does not represent the actual cost to a retail pharmacy of acquiring the drug. It is merely a wholesale list price that can be used as a benchmark in comparing retail and wholesale prices."[88]

Hence, the fact that AWP should not be literally interpreted as an average price paid by pharmacies to wholesalers has long been widely publicized and communicated by various government organizations monitoring federal government reimbursements for prescription drugs. This has not been a secret.

68. Before leaving this section, I believe it is useful to digress briefly and distinguish Medicare/Medicaid reimbursement for generic/multisource self-administered drugs vs. that for brand/single source drugs. Federal Medicaid provisions do not dictate the precise amount a state may pay for a given drug, although they do place limits on what the federal government will match. In 1987 Medicaid regulations established the federal upper limit (FUL), which set limits on the amount that Medicaid could reimburse for drugs with three or more generic versions.

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[87] Congressional Budget Office [1996], supra, p. 20, Box 2, "Comparing the Average Manufacturer Price with the List Price". Italics in original. After the word *Redbook,* the CBO appended a footnote 1, containing the statement: "Medical Economics Data, 1994 *Redbook* (Montvale, N.J.: MED, 1994)."

[88] U. S. Department of Health and Human Services, Report to the President [2000], *supra*, p. 101. At the end of this paragraph, the original text appends a footnote, stating "In establishing upper payment limits for state Medicaid programs, HCFA assumes that AWP overstates actual acquisition costs by 10 to 20 percent. (State Medicaid Manual, sec. 6305.1)"

Over the years the way in which FUL has been established has changed. States may set their own payment ceilings for these drugs, provided they do not exceed the federal payment limit.[89] Many state Medicaid programs have established their own lists of maximum reimbursement prices for generic self-administered drugs, which are typically also called MAC (maximum allowable cost) programs.[90] These state-specific programs also establish dispensing fee and patient copayment policies, which vary considerably among the states.[91] As a general rule, the state-specific lists typically include more drugs, list newly available generic drugs more quickly, and establish more aggressive (i.e., lower) reimbursements than does the FUL list.[92]

69. For example, a recent study by the Office of the Inspector General found that of the top 200 multisource drugs (based on retail sales for the year 2001) dispensed in the US, 90 drug products met the established criteria for inclusion, but in fact were not included on the FUL list in 2001.[93] As part of the Omnibus Budget Reconciliation Act of 1990, Congress mandated that drug manufacturers sign a rebate agreement with the federal government in order to receive payment for outpatient prescription drugs provided to Medicaid beneficiaries. Although there can be some waivers, in exchange states must cover all Food and Drug Administration-approved prescription drug products manufactured by a company that has signed a rebate agreement.[94] For generic manufacturers, the rebate is 11 percent of the product's Average Manufacturer's Price

[89] See Dawn M. Gencarelli, "Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?", *National Health Policy Forum*, Issue Brief No. 775, June 7, 2002, Washington DC: George Washington University, and the references cited therein for further details.
[90] For a description of state-specific MAC programs in 2003, see National Pharmaceutical Council, *Pharmaceutical Benefits 2003*, p. 4-42.
[91] National Pharmaceutical Council, *Pharmaceutical Benefits 2003*, p. 4-41.
[92] See, for example, Richard G. Abramson, Catherine A. Harrington, Raad Missmar, Susan P. Li and Daniel N. Mendelson, "Generic Drug Cost Containment in Medicaid: Lessons from Five State MAC Programs," *Health Care Financing Review,* 25(3), Spring 2004, pp. 25-34.
[93] Department of Health and Human Services, Office of Inspector General, *Omission of Drugs From The Federal Upper Limit List in 2001*, OEI-03-02-00670, February 2004.
[94] Dawn Gencarelli [2002], *supra*, p. 8.

("AMP"), while for branded, single source drugs, the rebate formula is more complex.[95] For both generics and brands, the AMP is computed as follows:

> "AMP is the average price paid to manufacturers by wholesalers (after all discounts, including manufacturer rebates) for a particular dosage form and strength of a prescription drug distributed solely to the retail pharmacy class of trade. The AMP is not a published price. It is calculated by the manufacturer and submitted to CMS for purposes of calculating the Medicaid rebate. The government holds it confidentially to protect the proprietary nature of the deals negotiated between manufacturers and their best customers. AMP is subject to government audits, making manufacturers accountable for its accuracy."[96]

70. Over the years the OIG has issued a number of reports documenting the acquisition costs to pharmacies of generic drugs dispensed to Medicaid recipients. For calendar year 1994, the OIG estimated that the average discount off AWP at which pharmacies purchased generic drugs was 42.45%; by 1999, this average discount off AWP for generic drugs increased to 65.93% (excluding non-traditional pharmacies, defined as nursing home pharmacies, hospital pharmacies, home IV, etc.). In both years these national averages also masked modest differences by class of trade and geography. Specifically, the 1994 (1999) averages discount off AWP for rural-chain pharmacies was 47.51% (64.39%); for rural-independent pharmacies it was 47.38% (66.64%); for urban-chain pharmacies it was 37.61% (66.97%); and for urban-independent pharmacies it was 46.72% (63.70%). The largest average discounts off AWP were obtained by the non-traditional pharmacies (defined above) – 57.70% in 1994 and 67.07% in 1999.[97]

71. A subsequent OIG analysis of the 1999 data revealed that if the drugs were disaggregated in a slightly different way, while certain patterns became apparent, considerable

[95] Dawn Gencarelli [2002], *supra*, pp. 8-9.
[96] Dawn Gencarelli [2002], *supra*, pp. 8-9. It is my understanding that AMP also includes drugs dispensed via mail order to commercial health plans/insurers/PBMs.
[97] Department of Health and Human Services, Office of Inspector General, *Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products*, A-06-01-00053, March 2002, p. 4.

heterogeneity persisted. Specifically, for single source drugs, the average discount off AWP was 17.2%, although the range was from 13% to more than 22%, with modest variability across class of trade, rural vs. urban, and by state. For multiple source drugs without FULs (including both brands and some generics), the average discount (excluding non-traditional pharmacies) was 42.03%, masking more substantial differences between urban-independent (37.10%) and urban-chain (45.56) average discounts. However, for multiple source drugs with FULs (primarily generics), the average discounts off AWP were much larger, averaging 72.13% (excluding non-traditional pharmacies). Again, these averages concealed considerable heterogeneity in average discounts by class of trade, rural vs. urban, and by state. [98]

72. Another study undertaken by a different federal agency, the Congressional Budget Office, and released just recently in December 2004, focuses on pharmacy markups ("the dollar difference between the total amount that Medicaid pays the pharmacy for each prescription and the amount that the pharmacy or wholesaler pays the manufacturer for the drug") between 1997 and 2002.[99] Since I have discussed this paper earlier in this report, I will not elaborate on it further here, other than to repeat its central findings, that "Between 19977 and 2002, by CBO's estimates, the average markup increased by nearly 60 percent – rising from $8.70 to $13.80 per prescription, or by about 9.7% per year", and that the markup depended not only on brand vs. generic, but also on the vintage of the generic (continuing generic, new generic drugs introduced by 2000, and new generic drugs introduced by 2002). The CBO summarized this finding as follows::

[98] Department of Health and Human Services, Office of Inspector General, *Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products*, A-06-02-00041, September 2002, various appendices.
[99] Congressional Budget Office, *Medicaid's Reimbursements to Pharmacies for Prescription Drugs*, December 2004, p. 1.

> "Much of the increase in the average markup was attributable to the use of relatively new generic drugs. For generic drugs that came on the market between 1997 and 2002, Medicaid reimbursed pharmacies an average of about $46 per prescription in 2002, of which only about $14 went for the purchase of the drug itself. Pharmacies and wholesalers retained the remainder, or markup, of about $32 per prescription."[100]

73. I conclude, therefore, the fact that AWP very substantially overstates pharmacies' actual acquisition costs for generic self-administered drugs has long been publicly available information, as has the fact that the extent of overstatement has been growing over time. There is also substantial, perhaps growing, heterogeneity in the extent of discounting off AWP among different pharmacy classes of trade, rural vs. urban, by state, and by whether the multisource drug was on the FUL list.

D. Why the Continued Confusion Concerning What is AWP?

74. Despite the fact that apparently most knowledgeable industry observers have long understood and taken into account in their decision-making that no one (except perhaps Medicare and the cash-paying retail customer) pays a price for branded drugs as high as AWP,[101] this knowledge is not universally held, and some confusion still remains. Depositions in this litigation document this confusion.

75. In the attachments accompanying *Plaintiffs' Reply Memorandum in Support of Class Certification* summarizing testimony from individuals deposed in this litigation, the record reveals a number of deponents testified in a way indicating they clearly understood that WAC was less than AWP and that pharmacies typically acquired drugs at prices considerably less than

[100] Congressional Budget Office, *Medicaid's ts to Pharmacies for Prescription Drugs*, December 2004, p. 1.
[101] Interestingly, in the simulation model of the PBM industry used by Banc of America Securities, it is stated that "…we assume AWP to be equal to average retail price (coincidentally this is often, approximately the case)". In particular, AWP is set equal to "Listed retail price". See Banc of America Securities, *Pharmacy Benefit Managers: Keeping a Lid on Drug Costs*, Health Care Technology and Distribution Industry Overview, February 2002, Figure 12, p. 21.

AWP; see, for example, testimony from deponents Gregory Madsen from Caremark;[102] Rena Maxwell from University of Pittsburgh Medical Center;[103] Bob Schultz from Blue Cross Blue Shield of Wyoming;[104] Carol Sidwell from John Deere, Inc.;[105] and Dale Kramer from Kaiser Permanente.[106] On the other hand, testimony from a number of other deposed individuals indicated they interpreted AWP more literally, as some average of wholesale prices charged by wholesalers and/or paid for by pharmacies to wholesalers, or prices paid by wholesalers to manufacturers; see, for example, the testimony by Linda Montefort from Empire Blue Cross Blue Shield of New York;[107] David Thomas from Three Rivers Health;[108] Dan Dragalin from Multiplan, Inc.;[109] Richard Francis from Harvard Pilgrim Health Care;[110] and Daniel Ryan from the United Food and Commercial Workers.[111]

76. Plaintiffs' Counsel have even noted that in the glossary of the 1999 textbook authored by Defendants' Expert Robert P. Navarro, the following definition is given:

> "AWP – average wholesale price; the standard charge for a pharmacy item; derived by taking the average cost of the item to a pharmacy as charged by a large representation of pharmacy wholesale suppliers (for items not otherwise being sold at a discount)."[112]

On the other hand, Plaintiffs' Expert Dr. Stephen Schondelmeyer has previously written that while AWP is not literally the average price paid by pharmacies for prescription drugs, the

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[102] *Plaintiffs' Appendix of Summary Charts in Support of Class Certification*, December 16, 2004, Exhibit 1a, p. 8. Hereafter I will call this set of deposition summaries as "Plaintiffs' Appendix 1a [2004]".
[103] Plaintiffs' Appendix 1a [2004], *supra*, pp. 9-10.
[104] Plaintiffs' Appendix 1a [2004], *supra*, pp. 12-13.
[105] Plaintiffs' Appendix 1a [2004], *supra*, p. 13.
[106] *Plaintiffs' Appendix of Summary Charts in Support of Class Certification*, December 16, 2004, Exhibit 1b, pp. 13-16. Hereafter I will call this set of deposition summaries as "Plaintiffs' Appendix 1b [2004]".
[107] Plaintiffs' Appendix 1a [2004], *supra*, pp. 10-11.
[108] Plaintiffs' Appendix 1a [2004], *supra*, p. 15.
[109] *Plaintiffs' Appendix of Summary Charts in Support of Class Certification*, December 16, 2004, Exhibit 1c, p. 1. Hereafter I will call this set of deposition summaries as "Plaintiffs' Appendix 1c [2004]".
[110] Plaintiffs' Appendix 1c [2004], pp. 1-2.
[111] Plaintiffs' Appendix 1c [2004], p. 3.
[112] As cited in Class Plaintiffs Memorandum in Support of Their Motion to Strike Portions of the Declaration of Robert P. Navarro, , In Re Pharmaceutical Industry Average Wholesale Price Litigation, MDL No. 1456, Relates to 01-CV-12257-PBS, December 17, 2004.

relationship between these list prices and actual acquisition costs is "constant" over time. Specifically, when introducing the National Association of Chain Drug Stores PRIME price index for the "Top 200 drugs by 1991 dollar volume sold through community pharmacies" based on Medi-Span list price data, he wrote:

> "Even though the AWP does not represent the actual price paid by pharmacies for drug products, there is typically a constant relationship between these list prices and the actual acquisition cost for most pharmacies. Manufacturers nearly always raise their list prices and their actual transaction prices to traditional community pharmacies at the same rate. Manufacturers' price change patterns have been monitored to identify and adjust for those cases where list prices and direct prices appear to have changed at a different rate."[113]

77. Part of the continued confusion apparently emanates from statements made by First DataBank, a publisher of AWP prices. For example, in the September 1991 issue of a First DataBank's publication, in an article entitled "Understanding AWP", the following definition appears:

> "AWP represents an average price which a wholesaler would charge a pharmacy for a particular product. The operative word is average. AWP never means that every purchase of that product will be exactly at that price. There are many factors involved in pricing at the wholesale level which can modify the prices charged even among the same wholesaler. AWP was developed because there had to be some price which all parties could agree upon if machine processing was to be possible."[114]

78. Essentially the same definition of AWP is given today. For example, the American Society of Consultant Pharmacists' website contains an "AWP Briefing Room" backgrounder on "AWP Changes for intravenous, inhalant and injectable Medications" in which information is

[113] Stephen W. Schondelmeyer, "The NACDS *PRIME* Index: Tracking Changes in Drug Prices", prepared for National Association of Chain Drug Stores, August 14, 1992, pp. 1-2. Italics in original. I note that elsewhere Professor Schondelmeyer has stated that the meaning of price terms have changed over time. See, for example, Schondelmeyer and Wrobel [2004], *supra*, p. 13.

[114] *First DataBank Monthly Interest*, "Understanding AWP", Vol. 6, No. 9, September 1991, p. 1. FDB-AWP 28850-28852.

given "on how AWP is calculated" by First DataBank ("FDB"). This internet search process yielded the following statement:

> "I have many conversations regarding what is 'AWP' and how does FDB determine it. There is much folklore and misunderstanding as to the determination of AWP and where we get the data.
>
> AWP is the average **wholesale** price. That is, AWP is the average of the prices charged by the national drug wholesalers for a given product (NDC). The operative word is **average**. AWP was developed to provide a price that all parties could agree upon for electronic processing to be possible.
>
> In order to determine the AWP, First DataBank surveys national wholesalers to ascertain what they use as a price basis in their AWP files. We contact the wholesalers to determine what the markup should be for a new company or to confirm that the markup that we are applying is current. A survey may be performed on a single NDC number or for a manufacturer's entire line of products. In either case, each national wholesaler is surveyed on a number of products from each manufacturer.
>
> The number of surveys performed is increasing. First DataBank surveys drug wholesalers that represent over two-thirds of the wholesaler total dollar volume. The markup that First DataBank utilizes is representative of wholesalers on a national level. Because individual wholesalers may mark up each manufacturer differently, a weighted average, not a consensus average, is calculated. That is, the market share held by the wholesalers surveyed affects the markup proportionally. Wholesalers with higher drug dollar volumes have more weight in the determination of the final markup. Thus, a higher degree of certainty is achieved. We also consider the manufacturer's suggested wholesale price (SWP) in our determination."[115]

79. At the First DataBank website "Frequently Asked Questions", under the question "How does First DataBank determine the Net Wholesale Price, Direct Price and Blue Book AWP as published in NDDF Plus and PriceProbe?", the following statement was retrieved in January 2005:

> "The Net Wholesale Price (also known as the wholesale acquisition cost or wholesale price) represents the manufacturer's published price for a drug product

[115] *Average Wholesale Price*, as found on the American Society of Consultant Pharmacists website, with a note this was last modified on 06/05/00. Online at http://www.ascp.com/public/ga/awp/awpinfo.shtml, accessed 1/22/2005. Boldface in original.

> to wholesalers. The Direct Price represents the manufacturer's published price for a drug product to non-wholesalers.
>
> First DataBank defines the 'Blue Book Average Wholesale Price,' which is commonly used as AWP, as the average of prices published by wholesalers to their customers for a given product. To determine Blue Book AWP, First DataBank typically identifies the Net Wholesale Price (or in some cases, the Direct Price) of a product, and then surveys the full-line national wholesalers to determine the average mark up applied to the manufacturer's line of products or a specific product. Such surveys may be conducted at the request of our customers or when a change in the marketplace occurs (such as a merger of manufacturers) which might occasion a change in prices. First DataBank does not include regional wholesalers or specialty distributors in its survey.
>
> First DataBank's Blue Book AWP is not intended to represent the wholesale price suggested by the manufacturer. Instead, First DataBank reports the manufacturer's suggested wholesale prices in a separate data field known as 'SWP.' In some cases, if manufacturers do not sell to wholesalers or if wholesalers agree with the manufacturer's suggested wholesale price, the Blue Book AWP and SWP may be the same.[116]

80. Two further examples illustrate factors contributing to the continuing confusion and ambiguity concerning AWP. First, in the 2000 edition of Novartis' Pharmacy Benefit Report, an industry trade publication, the glossary defines AWP as follows:

> "Average wholesale price (AWP) -- A published suggested wholesale price for a drug, based on the average cost of the drug to a pharmacy from a representative sample of drug wholesalers. There are many AWPs available within the industry, AWP is often used by pharmacies to price prescriptions. Health plans also use AWP – usually discounted – as the basis for reimbursement of covered medications."[117]

Second, a more recent widely cited California HealthCare Foundation report (prepared by a well-known health care consulting firm) contains the following glossary definition:

> "Average wholesale price (AWP) – A list of benchmark prices set by averaging across the spectrum of prices charged to pharmacies by wholesalers for both brand-name and generic drugs. The current list price is published in recognized

[116] First DataBank "Frequently Asked Questions". Accessed online at http://www.firstdatabank.com/customer_support/faqs, on January 20, 2005.
[117] *Novartis Pharmacy Benefit Report: Facts & Figures*, 2000 Edition, East Hanover, NJ, Novartis Pharmaceuticals Corporation, p. 43.

sources, including Medi-Span, FirstData Bank and its supplements, and Medical Economics' Red Book."[118]

81. It appears, therefore, that inconsistent and ambiguous information exists even currently concerning what type of price AWP measures. The continuing confusion is real and understandable.

E. Other Uses of AWP

82. In the previous paragraphs I have considered AWP in the context of sending signals on the structure of prices for self-administered drugs to potential purchasers. Several other uses of AWP exist, and in some cases these uses are likely to constrain the extent to which manufacturers face incentives to "artificially inflate" their AWPs. In other cases, published guidelines recommend use of AWP, and even the FDA suggests use of AWP. I provide examples in Attachment C.

F. Physician-Administered Drugs: Medicare Part B and Private Coverage

83. To this point, I have focused attention almost exclusively on self-administered single and multisource drugs. I have done so in part because I infer that the potential size of the class consisting of AWPID self-administered drugs is likely to be much larger than that for AWPID physician-administered drugs. An additional reason for beginning with self-administered drugs is that their distribution and benefit management differs markedly from that for physician-administered drugs, and combining the two into one discussion could mask their differences.

84. Some drugs are manufactured in both self-administered (e.g., tablets and capsules) and physician-administered (e.g., injectable) formulations. Even some injectable formulations can be either self-administered or physician-administered, depending on the health of and training

[118] California HealthCare Foundation, *Navigating the Pharmacy Benefits Marketplace*, Prepared by Mercer Human Resource Consulting, January 2003, p. 39. Available online at http://www.chcf.org/documents/hospitals/NavPharmBenefits.pdf.

received by the patient. For the moment, I will follow the CMS convention that a self-administered drug is one that is administered by the patient more than 50 percent of the time.[119] By physician-administered, I do not necessarily imply that the attending physician actually performed the procedure, but rather that it was done in a physician's office (perhaps by a nurse or nurse's aide) and billed by the physician.

85. By way of background, under Part B of Medicare, Medicare covers certain drugs administered in physician offices, used as part of durable medical equipment or infusion devices, as well as some oral drugs used following organ transplants. Medicare-covered outpatient drugs are mainly used in cancer treatment, dialysis, organ transplantation, and hemophilia.[120] Medicare reimburses physicians for 80% of the charges, while patients' coinsurance payments comprise the remaining 20%, once they meet the annual Part B $100 deductible; often the patients' coinsurance portion is supplemented by additional "MediGap" or other "wrap around" insurance policies that cover all or portions of the 20% coinsurance payments..

86. In 1999, Medicare and its beneficiaries spent $3.9 billion on prescription drugs; with a 20% patient coinsurance ratio, beneficiary payments were less than $1 billion, less than 1% of total drug expenditures in the U.S. at that time;[121] in 2000 the Medicare Part B expenditure grew by about 25% to $5.09 billion, by another 25% in 2001 to $6.41, and in 2002 it was projected to grow by 33% to $8.5 billion, comprising about 3% of total Medicare spending.[122] While in levels and share still relatively small, the Medicare Part B growth in drug expenditures has been very substantial, and has therefore attracted considerable attention.

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[119] Dawn Gencarelli [2002], *supra*, fn. 6, p. 16.
[120] "Medicare payments for outpatient drugs under Part B", ch. 9 in Medicare Payment Advisory Commission, *Report to Congress: Variation and Innovation in Medicare*, June 2003, p. 150. Hereafter I will refer to this chapter as MedPAC [2003].
[121] *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, October 25, 2004, p. 55, Paragraph 158. A slightly larger $4.09 billion Medicare drug expenditure is reported in MedPAC [2003], *supra*, Figure 9-2, p. 154.
[122] MedPAC [2003], *supra*, p. 154.

87. Spending for Part B drugs is highly concentrated, with the top 35 drugs accounting for almost 90% of drug spending, and three specialties – hematology oncology, medical oncology and urology – accounting for more than half of the total billing in 2001. A substantial portion of these Part B drugs represent novel and recently FDA-approved treatments. Of the top twenty drugs covered by Medicare in 2001, seven had received FDA approval in 1996 or later.[123]

88. All together, Medicare covers about 450 drugs under its Part B benefits. Many of these drugs are not generally available through retail pharmacies, but are provided by physicians in their offices or through pharmacy suppliers that provide drugs used with durable medical equipment. According to MedPAC, they include:

- drugs not self-administered and furnished incidental to a physicians' service, such as prostate cancer drugs;
- certain cancer and antinausea drugs available in pill form;
- blood clotting factor;
- immunosuppressive drugs used following organ transplants;
- erythropoietin used to treat anemia in end-stage renal disease patients and cancer patients;
- drugs used as part of durable medical equipment or infusion devices like the albuterol used in nebulizers for asthma and other pulmonary diseases; and
- osteoporosis drugs provided to certain beneficiaries by home health agencies.[124]

89. This set of outpatient drugs contains many brand name drugs and biologicals for which no effective therapeutic competition exists, and thus they can be very expensive. In 2001, physician claims accounted for more than 80% of total Medicare expenditures for outpatient

[123] MedPAC [2003], *supra*, p. 150.
[124] MedPAC [2003], *supra*, pp. 150-151,

drugs. For some specialties, payments for Part B drugs represent a large portion of total Medicare payments: 72% of all Medicare payments to hematology oncologists and medical oncologists were for Part B drugs in 2001, while 64%, 43% and 31% of payments to hematologists, urologists and rheumatologists, respectively, were for Part B covered drugs.[125] Notably, about half of all cancer patients are covered by Medicare.[126]

90. A large portion of these physician-administered Part B drugs are frequently referred to as "specialty pharmacy" products. An industry trade study notes that while there are many definitions of specialty pharmacy products, the concept broadly encompasses:

- products used to treat chronic, high-cost, or rare diseases;
- pharmaceutical or biological products administered via any non-oral means (e.g., infusion, injection, transdermal);
- products manufactured with a biological basis (e.g., blood products, insulin, etc.);
- any products administered in a non-hospital setting, including physician office, specialty clinic or patient's home;
- injectable and infusion therapies delivered in a non-hospital setting;
- high-cost ($5,000 and up per patient per year) therapies; and
- therapies that require complex care, including special handling, patient education and continuous monitoring.[127]

Pharmacies specializing in selling specialty pharmacy products are known as specialty pharmacy providers or specialty pharmacies.[128]

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[125] MedPAC [2003], *supra*, p. 151.
[126] American Society of Clinical Oncology, *Reform of the Medicare Payment Methods for Cancer Chemotherapy*, Alexandria, VA, May 2001, p. 2.
[127] Atlantic Information Services, Inc., *Specialty Pharmacy: Stakeholders, Strategies and Markets*, edited by Susan Namovicz-Peat, Washington DC, 2003, p. 1. Hereafter I refer to this document as "AIS [2003]".
[128] AIS [2003], *supra*, p. 1.

91. Over the years Congress has authorized expanded Part B coverage; decisions by CMS and local Medicare carriers determine the specific drug products eligible for reimbursement, occasionally leading to significant regional differences in coverage.[129]

92. According to Defendants' Expert Steven J. Young, Medicare's pre-1992 reimbursement policy involved paying for physician services and drugs on a "reasonable charge" methodology, reimbursing the physicians' entire billed charge as long as it was deemed reasonable by the local Medicare carrier. In particular, that reimbursement policy resulted in physicians earning the difference between what they paid for the drugs and the AWP at which Medicare reimbursed them.[130] Apparently in June 1991, HCFA proposed that Medicare Carriers base payment for drugs at 85% of AWP, based in part on an OIG report that pharmacies were obtaining on average a discount of 15% off AWP, after making the assumption that physicians likely paid no more than pharmacists.[131]

93. In opposing this policy, some physician specialties argued that if reimbursed at only 85% of AWP, the ancillary costs of providing these Part B drug services would not be fully recouped. According to the American Society of Clinical Oncologists ("ASCO"), for example, increasingly in the 1980s chemotherapy treatments were moving from the hospital to outpatient departments and physician offices, aided in part by the introduction of new antinausea agents that mitigated the troublesome side effects of many toxic chemotherapies. With the vast majority of chemotherapy treatments occurring in outpatient settings, such as physicians' offices, oncologists argued that reimbursing them at less than AWP would not cover chemotherapy administration costs, such as mixing powdered toxic chemotherapies in an appropriate solution,

[129] MedPAC [2003], *supra*, p. 151. Examples of Congressional expansion of benefits are given on p. 152 of that document.
[130] *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, October 25, 2004, p. 55, Paragraph 160.
[131] American Society of Clinical Oncologists [2001], *supra*, p. 7.

"pushing" or infusing the drugs into the patient, consulting with the patient providing family and grief counseling, managing patient side effects, and maintaining proper inventories. Particularly since some of the common patent-protected cancer agents cost more than $10,000, inventory costs were often considerable.[132]

94. In any case, after receiving public comments, in 1992 HCFA adopted a uniform national payment system based on 100% of AWP, but also authorized surveys that were to report on physicians' Part B actual acquisition costs, as well as related office practice treatment service costs. Other proposals for changing the reimbursement basis for Medicare Part B drugs were also considered during the 1990s. Congress did not adopt a Clinton Administration proposal that Medicare Part B change payment from one based on AWP to one based on actual acquisition costs, nor did it adopt another proposal that Medicare lower the payment rate to 83% of AWP. [133]

95. In 1997, after considerable debate, Congress passed the Balanced Budget Act of 1997, in the process lowering Medicare payments for single source drugs and biologics to 95% of AWP. For drugs for which there are two or more competing brand name products (referred to as multisource drugs) or generic equivalents available, Medicare reimbursed at 95% of the lower of (a) the median AWP of all generic forms of the drug, or (b) the lowest brand-name product AWP.[134]

96. Medicare's reimbursement for physician-administered drugs has continued to be controversial. Under terms of the Medicare Modernization Act of 2003, beginning in January 2005, Medicare Part B drugs will be reimbursed at 106% of ASP (actual average manufacturers'

[132] American Society of Clinical Oncologists [2001], *supra*, pp. 2-9.
[133] American Society of Clinical Oncologists [2001], *supra,* pp. 8-9.
[134] MedPAC [2003], supra, pp. 153-154.

sales price),[135] although during the transition year of 2004 the basis for drug reimbursement was set at 85% of AWP.[136] However, there appears to be some confusion regarding how biotech products will be reimbursed, and how Medicare will calculate ASP may differ from how Medicaid calculates AMP.[137] What is apparently clear is that in recognition of the AWP-related cross-subsidy provided physicians administering Medicare Part B drugs, Medicare is also increasing physician service fees; in the case of inhalation drugs delivered by nebulizers, for example, the dispensing fee has increased from $5 to $57.[138] It is my understanding that MedPAC and/or OIG is to report on reimbursements as they affect oncologists and other specialties in the near future, and on the way in which ASP is calculated.[139]

97. In summary, with Medicare Part B physician-administered drugs there has been a long simmering controversy regarding the extent to which AWP-based reimbursements adequately compensated physicians for the costs of services they provided in administering the drug treatment. It is instructive to compare the bundling of payor payments for generic self-

[135] "New MMA methodology for drug prices is a big change for many payers", available online at http://www.managedhealthcareexecutive.com/mhe/article/articleDetail.jsp?id=136812, last accessed 2/6/2005.
[136] *Declaration of Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification,* September 3, 2004, Attachment D, p. 5. Also see MMA – Drugs Paid by Average Selling Price Beginning January 1, 2005, available at www.cms.hhs.gov/medlearn/matters/mmarticles/2004/MM3232.pdf, last accessed 2/6/05.
[137] An article reprinted from the January 2004 issue of Specialty Pharmacy News states: "For 2004, single-source biotech products administered in an outpatient hospital setting will be reimbursed at 88% of Average Wholesale Price (AWP) in 2004, and at 83% of AWP in 2005. Innovator multiple—source drugs will be reimbursed at a minimum level of 68% of AWP in both 2004 and 2005. And non-innovator multiple source drugs will be reimbursed at 46% of AWP in both 2004 and 2005. For all these calculations, the AWP used is as of May 1, 2003. In 2006 the form law calls for a new payment method to be developed to more accurately reflect the costs of acquiring, handling and storing drugs and biologicals. The new reimbursement system will be based on a market-based reimbursement rate known as Average Sales Price (ASP). ASP will be calculated from data provided by the manufacturers for drugs and biologicals administered in hospital outpatient settings." Available online at http://www.aishealth.com/DrugCosts/specialty/spnMedicareReform.html, last accessed December 28, 2004. The AMP is defined in a DHHS Rebate Agreement document, available at www.cms.hhs.gov/medicaid/drugs/rebate.pdf, last accessed 2/6/05. Details on the calculation of ASP for Medicare are found in the King & Spaulding document, "Drug Pricing and Reporting: The Next Compliance Challenge", available at www.kslaw.com/library/pdf/drugconferenceslides.pdf, , last accessed 2/6/05.
[138] An Orientation to the Acquisition of and Reimbursement for Prescription Drugs, Tutorial Submission of the Track One Defendants before Judge Patti B. Saris, by Gregory K. Bell, Ph.D. and Fiona Scott Morton, Ph.D., December 7, 2004, p. 36.
[139] United States Department of Health and Human Services' Office of Inspector General Issues "Work Plan Fiscal Year 2005", dated 1/11/3005, available online at http://www.agg.com/Contents/PublicationDetail.aspx?ID=1205, last accessed 2/7/05.

administered drugs to the bundle of payor payments to medical/physician providers for dispensing and administering drugs. Although the phenomenon of bundling ingredient cost and dispensing fee reimbursements to pharmacies to incentivize them to dispense generic drugs has apparently enabled both pharmacy and payer to benefit, for self-administered Medicare Part B drugs the bundling of ingredient cost and administration services into an AWP-based reimbursement has raised considerably more difficult and challenging issues, issues on which payer and provider are finding it more difficult to reach agreement. While I will not reproduce the histories here, it is also quite clear that knowledgeable observers understood that physicians were able to purchase many of the Medicare Part B outpatient drugs at acquisition costs considerably less than AWP.[140,141]

98. Physicians administer drugs not only to Medicare Part B patients, but also to non-Medicare patients, such as under age 65 individuals requiring nebulizers, or under-65 patients diagnosed with and treated for cancer. Commercial carriers typically negotiate reimbursements/payments with physician practices or other provider networks when such physician-administered drug services are provided. The record in this case is unsettled to date as to whether those payments to physicians for physician-administered drugs and related services are based predominantly on AWP (as has been argued by Plaintiffs' experts Raymond Hartman[142] and Professor Meredith Rosenthal[143]) or instead are negotiated as part of the overall

[140] For a review of some of the public studies, see MedPAC [2003], *supra*. Also see Attachment B to this report.
[141] Earlier in this report I quoted Professor Kolassa's [1994a] description of the perverse incentives facing any given generic manufacturer to attempt unilaterally to set its ex-factory prices close to its AWPs. While that description written quite some time ago, Plaintiffs have provided evidence that this incentive structure persists to the present today – at least in the context of physician-administered drugs; see, for example, the Dey Complaint (Dey is a generic specialty drug manufacturer) cited in P*laintiffs' Reply to Schering-Plough Group's Individual Memorandum in Opposition to Class Certification*, December 17, 2004, pp. 9-10.
[142] *Declaration of Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification,* September 3, 2004, Attachment D, p. 10, citing the Dyckman & Associates 2002 report, which reported AWP reimbursement rates from commercial carriers varying between 85% and 115% of AWP.

physician fee schedule involving both drugs and services, based on "charges" rather than on costs (as has been argued by Defendants' Expert Steven J. Young[144]). While I note the controversy here, I will not comment on it further at this time.

99. It is important to note, however, that very important differences exist between self-administered and physician-administered drugs involving their distribution and management. One of the more important differences concerns distribution logistics. Many physician-administered drugs are sold by manufacturers directly to physicians or to hospitals' outpatient departments; group purchasing organizations ("GPOs") often act as intermediaries between manufacturers and physicians/hospitals, although typically GPOs, like non-mail order PBMs, do not actually take title to the drugs.[145] Providers receive reimbursement for the drug as well as compensation for the services of administering the drug. Less frequent is the situation when specialty and retail pharmacies distribute the products directly to patients. In some cases pharmacies may provide the drug to physicians, but then receive reimbursement directly from the health plan/insurer, thereby eliminating the physician reselling transaction.[146]

100. A second major difference between self-administered and physician-administered drugs involves the fact that while PBMs have become crucial agents in impersonally and efficiently electronically adjudicating billions of prescriptions for self-administered brand and generic drugs, thereby serving as a behind-the-scenes invaluable intermediaries, the rapidly

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[143] Written tutorial of Meredith Rosenthal, Ph.D., before Judge Patti B. Saris, December 6, 2004, p. 10, citing the same Dyckman & Associates 2002 report, quoting it as saying "that most plans use a pricing formula that is in the range of 90% to 100% AWP, with the average at 98% of AWP."

[144] *Sur-Reply of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, January 20, 2005, pp. 6-21, and accompanying appendices.

[145] *Declaration of Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification,* September 3, 2004, Attachment C, p. 5; Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Introduction, Final Report, Contract #500-00-0049, Task Order 1, Cambridge, MA: Abt Associates Inc., August 30, 2004, pp. 10-11.

[146] *Declaration of Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification,* September 3, 2004, Attachment C, p. 5.

growing specialty pharmacy intermediaries have been characterized instead as being "high cost and high touch", meaning that they provide specialized delivery and administration services on an ongoing basis, typically more individualized than that involving self-administered drugs.[147] Consider several examples.

101. While the combined specialty pharmacy – PBM firm Advance PCS reports that patients with chronic diseases requiring specialty drugs comprise 1% to 5% of a typical health plan's population, these patients nonetheless accounted for 25% to 50% of the plan's total medical costs. For example, a patient requiring recombinant hemophilia factor on average has a drug therapy cost of $150,000 per patient year, but may cost up to several million dollars. Part of the challenge of managing such a patient is that with hemophilia, patient's required usage is typically difficult to predict, but when needed, the need is acute, so that managing inventory becomes a critical cost factor.[148]

102. A November 2001 article in the trade journal *Employee Benefit Plan Review* highlighted the rapid growth of specialty pharmaceutical sales, and noted that increasingly PBMs were developing alliances with or starting their own specialty pharmacies. The article noted recent alliances between Merck-Medco Managed Care and CVS' ProCare, AdvancePCS alliance with Priority Healthcare JV and its acquisition of TheraCon, and Express Scripts' founding of Specialty Distributions in 1998.[149]

103. In short, while self-administered drugs are managed electronically and impersonally via PBMs, for physician-administered drugs, the management is more

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[147] AIS [2003], p. 2.
[148] "AdvancePCS Views Its Specialty Rx as Complementary to Caremark's Approach", reprinted from the January 2004 issue of Specialty Pharmacy News, pp 2-3. Available online at http://www.aishealth.com/DrugCosts/specialty/SPNAdvancePCSComplementCaremark.html, last accessed 12/29/2004.
[149] "Specialty Drugs, Pharmacies: A Growing Trend", in *Employee Benefit Plan Review*, November 2001, 56(5), pp. 22-24.

individualized, and is increasingly done so by specialty pharmacies (who are increasingly aligning themselves with PBMs). I note in passing that since many of the physician-administered drugs are single-source, and the only product in their therapeutic class, to date rebates have been relatively rare. Apparently the extent to which manufacturers have been willing to provide rebates to specialty pharmacies has been increasing, with rebates ranging from 6% to 15% of WAC.[150] With rebates being relatively rare, the principal way in which plans can save costs is to manage the specialty pharmaceuticals closely.[151]

104. A third major difference between self-administered and physician-administered drugs concerns the insurance provisions under which benefits are provided. By definition, virtually all of the self-administered drugs are purchased and administered on the plan's prescription drug benefit, most of them involving a PBM. In contrast, approximately 70% of specialty drugs are purchased and administered on the medical side of the benefit.[152]

105. Reporting on an April 4, 2002 roundtable discussion hosted by Ancillary Care Management ("ACM"), AIS Health stated that "ACM claims that approximately two-thirds of the time, injectable drugs are covered under the major medical benefit, whereas only one-third of the time they are covered under the pharmacy benefit, and it may often be up to the health plan to decide where the benefit falls."[153] The article then went on to provide an example:

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[150] "Effective Plan Design Helps Keystone Get Specialty Rx Rebates", reprinted from the January 12, 2004 issue of Managed Care Week, p. 1. Available online at http://www.aishealth.com/DrugCosts/specialty/MCWKeystoneRxRebates.html, last accessed 12/28/2004.
[151] Atlantic Information Services, Inc., *Specialty Pharmacy: Stakeholders, Strategies and Markets*, Edited by Susan Namovicz-Peat, 2003, pp. 32-33. Hereafter I call this document AIS [2003].
[152] Various estimates of this medical vs. drug split of benefits for specialty drugs are given in AIS [2003], p. 84. Also see "Tenn. Blues Choose Three Specialty Rx Vendors, Create Product List", reprinted from the January 2004 issue of Specialty Pharmacy News, p. 3. Available online at http://www.aishealth.com/DrugCosts/specialty/spnTennBlues.html, last accessed 12/29/2004.
[153] [153] "Defining Specialty Pharmacy: Services, Market and Players," p. 5. Available online at http://www.findarticles.com/p/articles/mi_mONK/is_7_3/ai_89237271/print, last accessed 12/28/2004.

> "For instance, depending on the type of injectable, or whether the patient is enrolled in PPO- or HMO-based plans, Aetna members may receive the drug under either the pharmacy or medical benefit. In Aetna PPO-based plans, all covered self-injectable drugs are available under the standard pharmacy benefit. According to BioScrip, 40% of its managed injectables will be covered under the pharmacy benefit. As a result, there is no standard benefit management at this time for specialty pharmaceuticals, and in the future PBMs may have to establish consistent guidelines of how to manage the drug benefit."[154]

An *Employee Benefit Plan Review* news article predicted that because of the increasing awareness of specialty drugs by PBMs, as well as the growing alliances between specialty pharmacies and PBMs, a shift from the medical to the pharmacy benefit may accelerate, exposing perhaps the very high cost of the biotechnology drugs.[155]

106. Converting specialty products from the medical benefit to the pharmacy benefit is not always easy. RESTAT, a PBM, reports that while it was relatively easy to transfer new payments from medical to pharmacy benefits, that was not always so with patients who had an extended history of receiving the product under the medical benefit, for such patients often had cemented their relationship with their provider, and were hesitant to switch from physician-administered to self-administered. By manipulating the copay differential between medical and pharmacy benefits, in particular by lowering the patient copayment as the patient switched from physician to self-administered, the health plan was however able to make sure the product was purchased from the preferred specialty provider, rather than allowing the physician to purchase the product from a supplier of his or her own choosing.[156]

107. A fourth major difference between self-administered and physician-administered drugs concerns the very different roles played by the prescribing physician. While for self-

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[154] "Defining Specialty Pharmacy: Services, Market and Players," p. 5. Available online at http://www.findarticles.com/p/articles/mi_mONK/is_7_3/ai_89237271/print, last accessed 12/28/2004.
[155] "Specialty Drugs, Pharmacies: A Growing Trend", in *Employee Benefit Plan Review*, November 2001, 56(5), pp. 22-24.
[156] "Accelerating Pipeline Said to Drive Need for Payer SP Strategies", reprinted from the May 2004 issue of Specialty Pharmacy Times, pp. 2-3. Available online at http://www.aishealth.com/DrugCosts/specialty/SPNAcceleratingDriveNeed.html, last accessed 12/29/2004.

administered drugs typically the prescribing physician does not dispense the drug (instead, the pharmacy does), for physician-administered drugs the prescriber is typically also the dispenser, implying that a potential conflict exists between physicians attempting to provide cost-effective and appropriate treatments for their patients, and physicians acting as dispensers of drugs receiving the benefits of any differential between the drug's acquisition costs, and reimbursement received from Medicare Part B or a commercial payor. This creates a variety of problems. As one industry trade reference source states:

> "The management of injectable drug costs represents a challenge to managed care organizations, and the main reason is that physicians often are the providers for these medications. Further, these physicians are often specialists who have, over time, made substantial profits for the provision of these medications.
>
> And, unlike pharmacies with oral prescription drugs, these specialists represent a much greater challenge to contract with or to find alternatives for patient care. For example, it is easier to negotiate pharmacy network rates with chain and independent pharmacies for oral medications. This is because competition among prescription drugs is so fierce, and the abundance of pharmacies in the area can 'soften' the market prices.
>
> Specialist physicians, on the other hand, are less abundant and have deeper personal relationships with patients. Therefore, to negotiate a lower reimbursement or otherwise sever the patient-physician bond adds an extra dimension to the challenge of providing injectable drugs.
>
> In addition, these specialists typically contract with many different health plans. As such, no one plan represents a majority of business for that physician, so plans hold minimal leverage to demand special rates. In response to these challenges, some health plans have elected to use specialty drug companies to provide these drugs to physicians rather than paying the physicians for the provision of these drugs to patients."[157]

In the now highly visible scandals involving Lupron and Zoladex, the profit "spread" was gamed and marketed by manufacturers using terms such as "return to practice".[158] Without digressing into details of that case, here I simply want to point out that managed care organizations trying to

[157] AIS [2003], *supra*, pp. 72-73.
[158] See Judge Stearns statements in United States District Court, District of Massachusetts, MDL No. 1430, Master File No. 01-CV-10861-RGS, *In Re: Lupron Marketing and Sales Practices Litigation, Memorandum and Order on Defendants' Motion to Dismiss Corrected Consolidated Amended Class Action Complaint and Second Amended Consolidated Complaint.*

aggressively contain costs and ensure that their beneficiaries are obtaining cost-effective treatments face a tradeoff that is very different in their dealings with PBMs and self-administered drugs.

108. Specifically, with physician-administered drugs, health plans/insurers risk losing valued physicians from their specialty networks (with all the implications that has for the competitiveness and relative attractiveness of the plans they offer employers) if they move patients from medical to pharmacy benefits and contract through specialty pharmaceuticals or PBMs for purchasing these drugs, instead of letting physicians capture the benefits of purchasing the drugs themselves and implicitly reselling them to payors. As a result, payors may not be quite as aggressive in obtaining cost information about these drugs, as they would be were they dealing with pharmacy-dispensed drugs. I discuss this further in Section V below.

109. Interestingly, the specialty pharmacy literature provides considerable discussion of this conflict facing managed care organizations. One article, for example, noted that for a rheumatoid arthritis drug, some physicians in certain geographic regions of the US were reluctant to give up profits from self-dispensing the drug. In some areas of the US, there is apparently a shortage of rheumatologists, and in those areas the rheumatologists may have as much leverage as oncologists in contracting with specialty pharmacy vendors and health plans.[159] Other industry trade articles provided managed care organizations with advice and examples of how they had worked with payors to develop cost containment strategies and yet simultaneously not lose valuable specialist physicians from their networks.[160]

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[159] "Accelerating Pipeline Said to Drive Need for Payer SP Strategies", reprinted from the May 2004 issue of Specialty Pharmacy Times, p. 3. Available online at http://www.aishealth.com/DrugCosts/specialty/SPNAcceleratingDriveNeed.html, last accessed 12/29/2004.

[160] Illuminating articles in this context include Chris Nee, "Essentials for Cost-Effective, Win-Win Injectables Management", reprinted from the July 11, 2003 issue of Drug Cost Management Report, 4 pp. Available online at http://www.aishealth.com/DrugCosts/DCMRWinWin.html, last accessed 12/29/04; also see "Highmark's New 'Payer-Friendly' SP Firm Forecasts '04 Profits, Growth", reprinted from the January 2004 issue of Specialty

110. These important differences between the distribution and management of self-administered vs. physician-administered drugs have significant implications for information flows, competition and price transparency. In Section IV that follows immediately, I discuss competition, information flows and price transparency in the context of PBMs and self-administered drugs. I defer to Section V an associated discussion of information, price transparency and competition in the context of self-administered drugs.

IV. PBM COMPETITION AND PRICE TRANSPARENCY: SELF-ADMINISTERED DRUGS

111. In Section III, Subsections A, B and C I have noted that information concerning the extent of the spread between AWP and WAC, or AWP and ASP, for self-administered drugs has been widely although not universally diffused among manufacturers, retailers, payors, policy makers and PBMs. I now examine information and price transparency issues particularly associated with PBMs in their role as intermediaries managing purchases of self-administered drugs.

112. Plaintiffs' Expert Dr. Raymond Hartman argues that the pharmaceutical industry is plagued by "the lack of pricing transparency",[161] and that this is particularly true for PBMs who "possess strategic information advantages as a result of the central and critical position they occupy". He then asserts: "*The importance of control of this information cannot be understated, given the overall lack of pricing transparency in this industry.*" [162]

Pharmacy News, 5 pp. Available online at http://www.aishealth.com/DrugCosts/specialty/spnHighmark.html, last accessed 12/29/04.

[161] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, 16 December 2004, p. 4.

[162] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, 3 September 2004, Attachment C, p. 11. Italics in original.

113. Over the years, PBMs have been the focus of considerable scrutiny from the U.S. Department of Justice ("DOJ") and the Federal Trade Commission ("FTC"), from states' Attorneys General, and from other private players in the health care system. In these contexts, it is useful to distinguish three situations in which informational asymmetries could potentially harm competition, and the actions that have been taken over the last decade by governmental and private sector agents regarding information flows and competition: (i) drug manufacturers acquiring a PBM and thereby becoming vertically integrated; (ii) large PBMs, not owned by drug manufacturers, merging with each other; and (iii) large PBMs, not owned by drug manufacturers, vertically integrating with mail order pharmaceutical distributors. I now consider each of these, in turn, all in the context of self-administered drugs.

A. Information with Vertically Integrated Drug Manufacturers and PBMs

114. In 1993, Merck & Co. acquired Medco Containment Services, thereby becoming the first vertically integrated drug manufacturer – PBM; Merck named its subsidiary Merck-Medco Managed Care, LLC. About a year later, SmithKline Beecham acquired Diversified Pharmaceutical Services ("DPS"). Soon thereafter, Eli Lilly and Company acquired PCS, another PBM, from the McKesson Corporation. Other manufacturers entered into alliances with PBMs, such as Pfizer with ValueHealth.[163]

115. These mergers attracted the attention of the Federal Trade Commission ("FTC"), and over the years have resulted in a number of investigations. FTC activities up through 1999 are discussed by FTC economist Roy Levy, who focuses in particular on how "revolutionary developments in information technology" affected PBMs' relationships with not only

[163] *HCFA Study of Pharmaceutical Benefit Management*, Contract No. 500-97-0399/0097, Federal Project Officer, Dr. Peri Iz, June 2001, p. 23. Online at www.cms.gov/researchers/reports/2001/cms.pdf, accessed January 14, 2005.

manufacturers, but also with wholesalers, retailers, physicians and other providers, and payers.[164] While the FTC recognized that PBMs facilitated price competition by, for example, using formularies and information technology that enabled real-time substitution among alternative prescription drug treatments, the FTC also worried publicly about the PBMs' combination of access to competitor information and information that might facilitate information exchanges among drug companies, thereby enhancing the likelihood of price coordination that could harm consumers.[165]

116. In 1995 the FTC challenged aspects of the vertical acquisition of PCS Health Systems by Eli Lilly & Co., obtaining a consent decree, and establishing a "firewall" between Lilly and PCS. At that time the FTC also pledged to monitor the PBM industry carefully, and cautioned that it might take future action if it concluded there were signs of anticompetitive conduct in the industry. In August 1998 the FTC announced an agreement with Merck & Co. and its subsidiary, Merck-Medco Managed Care, resolving FTC antitrust concerns, again obtaining a consent agreement establishing a "firewall" between drug manufacturer and PBM. In both cases, the drug manufacturer agreed to maintain an open formulary that included drugs selected and approved by an independent Pharmacy and Therapeutics ("P&T") Committee.[166] Apparently, upon acquiring the PBM Diversified Pharmaceutical Services, SmithKline Beecham voluntarily agreed to similar provisions, including construction of a similar firewall.[167]

117. Whether for reasons due to potential PBM clients being skeptical and cautious, or because of successful FTC regulatory intervention, or both, the merged PBM-manufacturer

[164] Roy Levy, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change*, Washington DC: Bureau of Economics Staff Report, Federal Trade Commission, March 1999, p. ix.
[165] Levy [1999], *supra*, p. 100, 140.
[166] Press Release, "Merck Settles FTC Charges that Its Acquisition of Medco Could Cause Higher Prices and Reduced Quality for Prescription Drugs", August 27, 1998. Online at http://www.ftc.gov/opa/1998/08/merck.htm .
[167] Levy [1999], *supra*, p. 102.

entities have not been sustainable, and instead several have given rise to spin-off merged retailer-PBM entities.

118. In 1999 SmithKline Beecham sold DPS to an existing PBM, Express Scripts, and Lilly sold PCS to chain drug retailer Rite Aid (who one year later sold PCS to PBM Advance Paradigm, creating AdvancePCS). Both Lilly and SmithKline Beecham divested their PBMs for significantly less than they were acquired. Lilly, for example, reduced the book value of its PCS Health System PBM by $2.4 billion, more than 50% of its initial $4.1 billion purchase price, prior to selling it to Rite Aid. Citing press accounts, an FTC report suggests that Lilly may have been "mistaken about the ability of PCS to expand its drug sales" and that other drug manufacturer acquisitions of PBMs "led to changes in prescription drug sales that fell short of expectations".[168] The FTC then comments on this vertical integration experience as follows:

> "The reduction in Lilly's book value, as well as its recent sale of PCS to Rite Aid Corporation, equally calls into question whether this vertical merger led to higher prices or profits from anticompetitive foreclosure. This may simply reflect the success of regulatory intervention. {Footnote Not Reproduced}. Alternatively, it may mean that exclusionary practices, such as efforts by vertically integrated drug companies to limit competitor access to the drug formularies of downstream PBM affiliates, {Footnote Not Reproduced}, were not successful in achieving anticompetitive foreclosure in this case {Footnote Not Reproduced}. In short, Lilly's decision to mark down the book value of PCS offers little support for either an efficiency or an anticompetitive interpretation of that transaction.[169]

119. Instead of vertical integrations involving drug manufacturers and PBMs, we now observe retailer-PBM vertical integrations. Chain retailer Eckerd now operates Eckerd Health Services, its PBM, as does CVS with PharmaCare, and Walgreens with Walgreens Health

[168] Roy Levy, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change*, Bureau of Economic Analysis, Federal Trade Commission, March 1999, p. 126.
[169] Levy, *supra*, p. 127.

Initiative. Chain grocer Kroger has a PBM named Kroger Managed Prescription Drug Program.[170]

120. Finally, in 2002 Merck & Co. announced its intention to spin-off its PBM subsidiary, and on August 12, 2003, Merck announced the completion of its spin-off of Medco Health Solutions, Inc.[171] To the best of my knowledge, Merck & Co., Inc. is not a defendant in this case, although Medco is.

121. Regarding these mergers between manufacturers and PBMs, Plaintiffs' Expert Dr. Raymond Hartman acknowledges "…this consolidation did not prove successful, and by 2003 the relevant manufacturers had divested their PBMs."[172]

B. Information with Horizontally Integrated Independent PBMs

122. PBMs have become central players in constructing, managing, and delivering drug benefits to insured populations. From relatively humble beginnings as regional electronic managers of transactions, PBMs have now evolved into full service, web-enabled, nation-wide pharmaceutical services organizations.

123. As shown in Exhibit A below, over the years the set of PBM service offering has expanded considerably, and these offerings increasingly place the PBM industry in a central position electronically linking pharmaceutical manufacturers, pharmacies, payors, physicians and patients. According to Defendant's Expert Steven J. Young, in 1994 58% of health plans contracted with PBMs, but by 1999 this proportion had increased to 90%. Moreover, "Today approximately 95% of all patients with drug coverage receive benefits through a PBM that has

[170] Banc of America Securities [2002], *supra*, pp. 15-16; HCFA Study of Pharmaceutical Benefit Management [2001], *supra*, p. 24.
[171] Press Release, "Merck & Co., Inc. Completes Spin-Off Of Medco Health Solutions, Inc.", online at http://www.merck.com/newsroom/press_releases/corporate/2003_0820.html, accessed 20 January 2005.
[172] Hartman [2004], *supra*, Attachment C, p. 9.

contracted with a commercial or government-sponsored plan."[173] PBMs have become ubiquitous actors in the management of purchases of self-administered drugs.

Exhibit A

Growth of PBM Service Offering

				Medicare Drug Plan
				Internet Content
				Specialty Pharmacy
			Disease Management	Disease Management
		Prior Approval	Prior Approval	Prior Approval
		Pharmacy Networks	Pharmacy Networks	Pharmacy Networks
		Drug Reviews	Drug Reviews	Drug Reviews
	Co-Pays	Co-Pays	Co-Pays	Co-Pays
	Mail Order	Mail Order	Mail Order	Mail Order
Claims Processing	Claims Processing	Claims Processing	Claims Processing	Claims Processing
1970's	**1980's**	**Early 1990's**	**Late 1990's**	**Future State**

Source: Goldman Sachs Global Equity Research, Healthcare: Supply Chain – Pharmacy Benefit Managers, United States, October 16, 2003, Exhibit 2, p. 4.

124. A Goldman Sachs Global Equity Research industry overview of today's PBM industry describes its central role as follows:

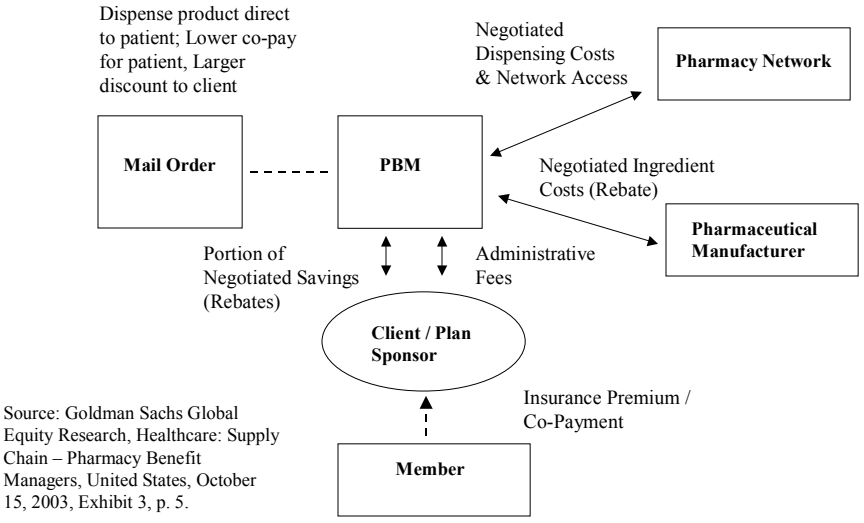
> "The demand of large populations (employee or managed care) for ubiquitous, flexibility, standardization and national access to pharmaceutical benefits drives the scale characteristics of pharmaceutical benefit managers. Linking hundreds of manufactures, thousands of products, and tens-of-thousands of retail dispensing points, demands sophisticated process management capabilities (think Automated Teller Machines – ATMs for drugs) with real-time access to patient billing and clinical data.

The same Goldman Sachs Global Equity Research overview graphically depicts the critical central actor role played by PBMs; below I reproduce their graphic as Exhibit B.

[173] Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification, October 25, 2004, p. 37.

Exhibit B

PBM Industry Flow Chart



Source: Goldman Sachs Global Equity Research, Healthcare: Supply Chain – Pharmacy Benefit Managers, United States, October 15, 2003, Exhibit 3, p. 5.

125. The central role played by PBMs makes it particularly important that the industry be competitive, and that information flows be sufficient to facilitate workable competition benefiting consumers. In part because of debate concerning the appropriate role of PBMs in helping to administer the new Medicare Part D drug benefits in the US, and because of antitrust concerns in the wake of a proposed merger involving two large PBMs, much attention has recently been focused on the PBM industry. In the paragraphs that follow I discuss the PBM industry structure, the extent of price and rebate transparency, and recent as well as known forthcoming FTC actions involving PBMs.

B. 1. Documentation of Continuing Diverse PBM Ownership

126. There has been and continues to be considerable diversity in the ownership structure of PBMs. This has important implications regarding the extent to which "secret" practices can be carried out on a sustained basis without being uncovered. First I document this

diverse ownership for the most recent time period (2002 to the present), then for the first quarter of 1999, and finally for 1995/1996.

127. Over the past few years (say, 2002 to the present) some PBMs have been essentially stand-alone entities; these include Medco Health (since the 2003 dissolution of Merck-Medco Managed Care), AdvancePCS, Express Scripts, Inc. and Caremark Rx, Inc.[174] A substantial number of PBMs are owned by managed care organizations; these include WellPoint Pharmacy Management (owned by WellPoint Health Networks), Aetna Pharmacy Management (Aetna), Prime Therapeutics (Blue Cross Blue Shield of Minnesota, Nebraska, North Dakota and Wyoming), Prescription Solutions (PacifiCare Health Systems), Anthem Prescription Management (Anthem), CIGNA Pharmacy Services (CIGNA HealthCare), Pharma-Link (Blue Cross Blue Shield of Kansas City) and First Health (First Health).[175] Still other PBMs are owned by retail pharmacy/grocery chains; these include Eckerd Health Services (owned by Eckerd), PharmaCare Management Services (CVS Pharmacy), RxAmerica (Longs Drug Stores Corporation, joint with Albertson's), Walgreens Health Initiative (Walgreens), and Kroger Managed Prescription Drug Program.[176] It appears that even some wholesalers own PBMs, e.g.,

[174] I note that recently Advance PCS was acquired by Caremark Rx. The proposed acquisition was announced on September 2, 2003. See Goldman Sachs Global Equity Research, *Healthcare: Supply Chain – Pharmacy Benefit Managers, United States,* October 16, 2003, p. 56, Exhibit 59, and p. 57. Apparently this merger was consummated in March 2004. See *Declaration of Stephen W. Schondelmeyer in Support of Plaintiffs' Motion for Class Certification*, September 2, 2004, p. 10, footnote 2.

[175] Credit Suisse First Boston Equity Research, *Down Low, Volume II – Quarterly PBM Thoughts*, February 9, 2004, Exhibit 29, p. 33. Also see Goldman Sachs Global Equity Research, *Healthcare: Supply Chain – Pharmacy Benefit Managers, United States,* October 16, 2003, pp. 10-12.

[176] Banc of America Securities, Equity Research United States, *Pharmacy Benefit Managers: Keeping a Lid on Drug Costs*", Health Care Technology and Distribution Industry Overview, February 2002, p. 16. Goldman Sachs Global Equity Research, *Healthcare: Supply Chain – Pharmacy Benefit Managers, United States,* October 16, 2003, pp. 10-12.

Managed Pharmacy Benefits, by wholesaler Cardinal Health,[177] and RESTAT, owned by wholesaler F. Dohmen Company.[178]

128. A January 2000 report commissioned by the Henry J. Kaiser Family Foundation, and conducted by Mathematica Policy Research Inc., identifies the 20 largest PBMs in the first quarter of 1999, ranked by the number of retail pharmacy prescriptions managed.[179] Based on information available from the PBMs websites, I was able to determine their ownership type as of the first quarter of 1999. The results of this search are given in Attachment D. As is seen there, as of 1999Q1, seven of the top 20 PBMs were independent (Express Scripts/Value Rx, Advance Paradigm, Caremark Prescription Services, Prescription Solutions, National Prescription Administrators, MedImpact/MedCare, and Prime Therapeutics), five of the top 20 were owned by managed care/insurer organizations (Aetna Pharmacy Management, Wellpoint Pharmacy Management,[180] RxPrime, Prudential Pharmacy Management, and Proserve), five of the top 20 were owned by retailers (PCS Health System, ProVantage, Eagle Managed Care, RxAmerica, and PharmaCare Network), two were owned by pharmaceutical manufacturers (Merck Medco Managed Care, and Diversified Pharmaceutical Services, although during 1999 DPS was in transition to being acquired by independent PBM Express Scripts Inc.), and one was owned by a wholesaler (RESTAT).

129. I note in passing that this Kaiser Family Foundation report characterizes the PBM industry in 1999 as follows:

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[177] Banc of America Securities, Equity Research United States, *Pharmacy Benefit Managers: Keeping a Lid o n Drug Costs*", Health Care Technology and Distribution Industry Overview, February 2002, Figure 10, p. 18.
[178] See Attachment D to this report, indicating that in 1999, RESTAT was ranked the 20th largest wholesaler.
[179] Henry J. Kaiser Family Foundation, *The Role of PBMs in Managing Drug Costs: Implications for a Medicare Drug Benefit*, Prepared by Mathematica Policy Research, Inc., January 2000, Table 1, p. 8. Available online at www.pharmacy.ca.gov/publications/pbm_kff_role.pdf, last accessed 1/28/05.
[180] Although I was not able to confirm this, I believe it to be the case that Wellpoint, the owner of Proserve, is affiliated with the managed care firm Wellpoint.

> "Our review of the literature indicated that the PBM industry is highly competitive, and this point was also emphasized by those we interviewed. Competition is particularly keen on the fees for basic services that PBMs provide, such as claims processing."[181]

130. Ownership diversity going back to earlier times can also be documented. A study commissioned by the Health Care Financing Administration and published in 1996 depicts this diversity at a point in the mid-1990s. Of 107 PBMs identified by the University of Wisconsin researchers from industry and insurance directories, 89 yielded sufficient information by which they could be characterized, including ownership typology, lives covered, and services offered. Table 1, below, reproduces data from that study concerning ownership and coverage as of 1995/1996. The study authors note that many PBMs reported their origin as being a managed care organization (mco), a retail pharmacy, or a PBM (uniting claims processing and related services). As of 1995/1996, PBMs owned by retailers covered 7.6% of lives, independent PBMs covered 20.6% of lives, together managed care organizations, home care and insurance companies covered 24.7% of lives, while drug manufacturers covered 35.8% of lives, and wholesalers 1.4%. The study authors also comment that the PBM industry was dynamic, and that new entrants, exits, mergers, and name changes made the industry a "moving target".[182] What was true in 1995/1996 appears still to be the case today.

131. In addition to ownership diversity, there has been heterogeneity in the extent to which PBMs engage in mail order operations, the proportion of covered lives receiving benefits via mail order, the range of PBM services offered (see Exhibit A above), and whether service was provided on a regional vs. national basis.[183] The HCFA – University of Wisconsin study

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[181] The Henry J. Kaiser Family Foundation [2000], supra, p. 41. The report goes on to remark, "That said, the industry is dominated by a few large firms that could have an advantage in the bidding process." Ibid.
[182] HCFA Master Contract HCFA-95-023/PK, *Assessment of the Impact of Pharmacy Benefit Managers*, HCFA Master Contract HCFA-95-023/PK, University of Wisconsin-Madison, Center for Health Systems Research and Analysis; 30 September 1996. U.S. Department of Commerce, National Technical Information Service, pp. 22-32.
[183] See, for example, the website of the Pharmaceutical Benefits Management Institute, which provides selected details on services offered by its members. Online at http://www.pbmi.com/pbmdir.asp, accessed 1/26/05. Also see

reported that for 1995/1996, most PBMs offered their clients a comprehensive set of services, of which mail order ranked in the top three in terms of prevalence.

Table 1

PBM Ownership Type 1995/1996 [a]

Ownership Type [b]	Number of PBMs	Number of Covered Lives [c]	Percent of Covered Lives [d]
Retailer	23	27,534,000	7.6%
Pharmacy Benefit Managers	8	74,350,000	20.6%
Insurance	7	38,500,000	10.7%
Managed Care Organization	6	46,900,000	13.0%
Home Care	4	3,260,000	1.0%
Manufacturer	4	129,300,000	35.8%
Other	2	15,007,000	4.2%
Wholesaler	1	5,000,000	1.4%
Unknown	33	20,314,325	5.6%
Total	89	360,810,325	100.0%

(a) Per reporting in *Managed Healthcare* (MHC) or *Business Insurance* (BI)
(b) Retailer = pharmacy chain, other retailer or group of retailers; PBM = independent PBM; Insurance = indemnity insurance industry; Managed care organization = HMOs, PPOs and related health care organizations; Home Care = providers of home care services; Manufacturer = pharmaceutical manufacturer; Other includes Caremark (owned by a medical practice management and consulting company) and the Cystic Fibrosis Association; Wholesaler = drug wholesaler or wholesaler group
(c) Number of covered lives reported by PBMs in the category
(d) Percent based on total number of covered lives reported by all PBMs reporting in the MHC (1996) or BI (1995) directories
(e) Source of table: HCFA Master Contract HCFA-95-023/PK. "Assessment of the Impact of Pharmacy Benefit Managers", Wisconsin University – Madison. Center for Health Systems Research and Analysis; 30 September 1996. U.S. Department of Commerce National Technical Information Service. Table III.7, p. 32.

"Mail-order rates, capabilities foster increased competitiveness among PBMs", Drug Cost Management Report, September 12, 2003, online at http://www.findarticles.com/p/articles/mi_mONKV/is_11_4/ai_108118251 , accessed 1/25/2005.

132. While prescription volume dispensed through mail order was relatively low, and variable within the sample of PBMs, the trend towards utilization of this channel of distribution was already clearly increasing.[184]

B. 2. Implications of Diverse Ownership for Preserving "Secret" Information

133. An important implication of the patterns of diversified ownership and heterogeneous scale and scope of operations among PBMs is that commercial information regarding common negotiable contractual terms, such as rebates, discounts, audit rights, fee structures, penalties, risk assignment and other services offered is widely dispersed. This makes it difficult for any important information to remain uncovered on a sustained basis.

134. Commercial information concerning PBMs contracting and operations is known not only directly by those clients who contract with PBMs, but also by the diverse PBM owners – sometimes independent, but also commonly insurers, managed care organizations, retailers and wholesalers, as well as by the numerous health benefit consultant firms (e.g., Mercer, Segal, Towers Perrin, Wyatt, Hewitt Associates) who assist these various entities. While confidentiality commitments may make the terms of a specific contract "secret", general knowledge concerning what is negotiable and what is the range of terms typically offered is widespread. The presence of these various entities, each familiar with various aspects of PBM operations and finances, acts as a market discipline on the individual PBMs, even the larger ones.[185]

[184] HCFA Master Contract [1996] *supra*, pp. 31-38.
[185] A 2003 Goldman Sachs industry analyst's report notes that consolidation among the Blue Cross – Blue Shield franchises not only has resulted in the Blues' captive PBM replacing a previously outsourced independent PBM (citing Anthem's acquisition of Trigot, which will be serviced beginning in 2004 by Anthem's internal PBM, a contract loss for Medco), but that managed care's internal PBMs are now also competing aggressively to provide PBM service to outside unaffiliated entities (citing PacifiCare Health Systems). See Goldman Sachs Global Equity Research, *Healthcare: Supply Chain -- Pharmacy Benefit Managers, United States*, October 16, 2003, pp. 12-13.

135. Nonetheless, the extent to which precise details concerning, for example, provisions of PBM rebate contracts with manufacturers, are publicly known is an important issue in this current litigation. I note in passing that this "lack of transparency" is common in other areas of the health care industries, such as managed care organization negotiated rates with hospitals, and those with general and specialty physician practices.[186] Lack of pricing transparency in prescription pharmaceuticals is also facilitated by the federally legislated prohibition of the reselling of any prescription drug that was previously purchased by a hospital or other "health care entity". This legislation thereby mitigates possible arbitrage operations that typically generate pricing information.[187] Outside of health care, there are other industries with legendary complex and seemingly non-transparent pricing, such as airlines. Thus it is useful to examine why and under what conditions lack of pricing transparency occurs. In the paragraphs that follow in this sub-section, I address this issue of price transparency involving PBMs.

136. First, it is useful to have a general idea of the relative importance of various revenue or "profit" sources for PBMs. A rough approximation to understanding the sources of PBMs "profits" can be obtained by examining industry analysts' reports. Recognizing the diversity among PBMs, along with numerous idiosyncratic accounting complexities, in 2002 one industry analyst estimated that for the PBM industry, the net revenue mix was as follows: Retail discounts accounted for 36% of net revenues, mail order retail margins 27%, manufacturer

[186] See, for example, David Dranove, M. Shanley and W. D. White, "How fast are hospital prices really rising?", *Medical Care*, 29(8), August 1991, pp. 690-696; Michael A. Morissey, "Do Hospitals and Physicians Charge Different Prices?", ch. 3 in Michael A. Morissey, *Cost Shifting in Health Care: Separating Evidence from Rhetoric*, Washington DC: The AEI Press, 1994; Alan Sorensen, "Insurer-Hospital Bargaining: Negotiated Discounts in Post-Deregulation Connecticut," *Journal of Industrial Economics*, Vol. 51 (2003) pp 469-490; Joseph P. Newhouse, *Pricing the Priceless: A Health Care Conundrum*, Cambridge, MA: MIT Press, 2002, especially ch. 3, "The Management of Moral Hazard and Stinting: Demand- and Supply-Side Prices,", pp. 79-103. Information issues are also discussed *in Improving Health Care: A Dose of Competition: A Report by the Federal Trade Commission and the Department of Justice*, July 2004, pp. 12-25.

[187] See the Prescription Drug Marketing Act of 1988, as described in the Department of Justice's Civil Resources Manual, available online at http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title4/civ00113.htm, last accessed 2/7/05.

rebates 22%, and administrative fees 15%.[188] The HCFA – University of Wisconsin 1996 study suggests two additional kinds of "rebates": revenues for sharing drug use information with manufacturers, and funds received by PBMs for projects sponsored by manufacturers.[189] The continued existence of these various revenue sources and the associated accounting complexities are corroborated by a recent New York Times report on employers uniting to curb prescription drug costs.[190] How the relative sizes of the PBM revenue sources are accounted for may depend on the way the revenue streams are structured, e.g., flat fee vs. a percentage of drug costs.

137. These various revenue sources suggests at least three sets of negotiated contracts involving PBMs:

(i) PBM with manufacturer regarding rebates, formulary details, information exchanges, auditing provisions, disease management services, other services;

(ii) PBM with retailers regarding the timing of and amounts reimbursed retailers for dispensing drugs (including for reimbursement of purchased ingredients, dispensing fees, other administrative fees), network services provided, drug utilization reviews, mail order provisions, professional performance measures and penalties; other terms (such as specialty pharmacy benefits) and claims processing details;

(iii) PBM with third party payor/insurer/employer regarding range of benefit plans offered, amounts received for managing beneficiaries' prescriptions dispensed at retail or mail order, copayment/ coinsurance arrangements, formulary development and management (particularly when the PBM client has a formulary differing from that of the PBM

[188] Banc of America Securities, Equity Research United States, *Pharmacy Benefit Managers: Keeping a Lid o n Drug Costs*", Health Care Technology and Distribution Industry Overview, February 2002, Figure 13, p. 22. Details are not given on how this was calculated, and over what time period.
[189] HCFA Master Contract [1996] *supra*, p. xvii.
[190] See "Employers Unite in an Effort to Curb Prescription Costs" by Milt Freudenheim, *The New York Times*, February 3, 2005, p. C3.

national formulary), timing of and amounts reimbursed PBM for providing retail and mail order dispensing of drugs to member beneficiaries, claims processing details, rebate schedules and rebate management, audit rights, disease management, drug utilization review, and other terms, including specialty pharmacy.

Additional contracts may simultaneously involve payors/employers, PBMs, and retail/mail order pharmacies.[191] Notably, one set of contracts not included here is that between insurers and providers (such as physician practice networks), particularly for specialty pharmaceuticals. As I understand it, PBMs are typically not yet directly a part of that contract negotiating process, although the specialty pharmaceutical area is undergoing rapid changes. I will return to specialty pharmaceutical issues in Section V of this report. The other set of contracts not included here is that between generic drug manufacturers and retailers.

138. In the current litigation, particular attention has been focused on both the first set of contracts, that between manufacturers and PBMs, and the third set, that between PBMs and third party payors, in both cases involving rebates and their transparency. I begin with the first set of contracts involving rebates – that between manufacturers and PBMs.

B. 3. Contracts Between PBMs and Drug Manufacturers: Rebate Transparency

139. The key issues addressed in PBM contracts with drug manufacturers are generally known; see, for example, Federal Trade Commission [1999].[192] The price and rebate provisions of these contracts typically use wholesale acquisition cost ("WAC") as a metric for determining

[191] A May 2001 California HealthCare Foundation study, conducted by William M. Mercer, Inc. reports that in surveys with employers covering issues such as formulary rebates, research studies and clinical/health management issues, the researchers found that "Almost all employers we spoke with are reluctant to enter into direct contracts with pharmaceutical manufacturers because they believe that an objective third party is necessary to evaluate and manage these arrangements." See California HealthCare Foundation, *Prescription Drug Coverage and Formulary Use in California: Different Approaches and Emerging Trends*, prepared by William M. Mercer, Inc., May 2001, p. 47. This may be changing, however, as noted in the previous footnote.

[192] Roy Levy, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change*, Bureau of Economic Analysis, Federal Trade Commission, March 1999, Table III.1, p. 52.

the transaction prices for the prescription drugs subject to the contract. Incidentally, the FTC defines the WAC as follows:

> "WAC refers to the wholesale list price of the prescription drugs, and often differs from actual transaction prices. Transactions prices would equal WAC if no rebates, discounts or any other credits or allowances apply to transactions involving a particular prescription drug."[193]

140. It is useful to distinguish two situations involving branded, patent-protected drugs. First, for those drugs for which there is no other strong competitor in the same therapeutic class (e.g., Viagra, until about a year ago, for erectile dysfunction), typically manufacturers are unwilling to negotiate rebates. In such cases the drug has such a clear advantage over existing drugs for a condition that it quickly becomes the standard of care, to the relative exclusion of existing drugs. Anthony Barrueta, Senior Counsel for Kaiser Permanente, a large health maintenance organization, has noted in hearings before the DOJ/FTC that:

> "Under these circumstances, there is little opportunity for a purchaser to stimulate competition among manufacturers. Manufacturers are roughly free to set launch prices, they rarely discount those prices, and purchasers are price takers."[194]

Since rebates are rare in situations such as this, whether information about them is transparent is a moot point.

141. A very different situation emerges, however, when several patent-protected drugs compete with each other in the same therapeutic area (as is now the case for three erectile dysfunction drugs, Viagra, Cialis and Levitra). Kaiser's Senior Counsel Anthony Barrueta calls this the "competing monopoly/oligopoly" stage, and notes that this is where the possibility for price competition arises. He describes this environment as follows:

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[193] Levy, *supra*, p. 52, footnote 124.

[194] "Pharmacy Benefit Management Companies (PBMs)", comments of Anthony Barrueta, Senior Counsel, Kaiser Foundation Health Plan, Inc., Oakland, California, before the FTC/DOJ Joint Hearings, Health Care and Competition Law and Policy, June 26, 2003, p. 1; accessed online on December 31, 2004 at www.ftc.gov/ogc/healthcarehearings/docs/030626barrueta.pdf.

> "This stage represents the lion's share of the market at any given time. Here, there are multiple similar drugs on the market, all still under market exclusivity protection. Depending on how similar the drugs are – that is, how substitutable they are for each other – organized purchasers have the ability to either switch patients in a medically appropriate manner among the drugs (if the drugs are highly substitutable) or at least start new patients on a preferred drug (if the drugs are similarly effective, but switching would be disruptive to therapy). In either case, there is a competitive opportunity that can be taken advantage of. This is the area where formularies can be applied for the greatest effect on overall costs."[195]

142. It is important to note, I believe, that this "competing monopoly/oligopoly" situation is not an economics textbook example of a pure monopoly (for here there are several oligopolists competing, although each with market exclusivity due to patent protection), nor for certain is it an economics textbook example of perfect or pure competition among firms producing a homogeneous commodity, with free entry and exit of firms, and where buyers and sellers all have equal information regarding price. Instead, with competing monopolists/oligopolists, products are differentiated, and entry and exit are regulated by, among others, the FDA. It is precisely this market condition, however, that is most likely to give rise to rebates, and thus raise issue regarding the transparency of any rebates.

143. Industry analysts at Banc of America Securities describe the context and great importance of this stage, and the role played by PBMs, as follows:

> "On a regular basis (in our example, once per quarter) the PBM will remind all the branded pharmaceutical manufacturers (with which it has agreements) of their most recent contract to receive volume-based rebates (retroactive discounts). The PBM informs each manufacturer of the relevant volume figures and is in turn paid rebates. We note that these rebates, which we estimate average 10% of the cost of the drug, are paid only on branded, multisource pharmaceuticals (multisource refers to those pharmaceuticals that have competition in the marketplace – e.g. Claritin, Allegra and Zyrtec). Only 50% of all branded pharmaceuticals fall into this category; the rest are sole-source pharmaceuticals for which there is no competition (e.g., Viagra)."[196]

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[195] Anthony Barrueta, *supra*, pp. 1-2.

[196] Banc of America Securities, Equity Research United States, *Pharmacy Benefit Managers: Keeping a Lid o n Drug Costs*", Health Care Technology and Distribution Industry Overview, February 2002, p. 21. Note here the

144. In such a situation, if competition is to be effective, how transparent are results of price negotiations likely to become, and are consumers harmed or do they benefit when discounts or rebates are "secret"? Are consumers better or worse off if forced transparency of prices is mandated? What should one expect regarding the transparency of prices negotiated between PBMs and competing monopolists/oligopolists? I turn now to a discussion of the desirability of pricing transparency in the context of buyers (particularly organized buyers, such as health care organizations) attempting to create price competition among monopoly/oligopoly sellers offering differentiated products. I begin with insights from economic theory, cite some experimental evidence, recount testimony from a large buying group, as well as summarize recent position statements made by the FTC involving the desirability of forcing pricing transparency among PBMs.

B. 3. a Price Transparency with Competing Oligopolists/Monopolists: Theory

145. Within the area of applied microeconomics commonly known as industrial organization, there is a long oral tradition that in the context of oligopolists offering differentiated products, concludes, seemingly paradoxically, that "the best deal is a secret deal". This line of reasoning is frequently associated with two seminal papers by economics Nobel Laureate George Stigler.

146. First, in a 1961 article entitled "The Economics of Information", Stigler examined the costs and benefits of searching for information, such as that on product quality and price.[197] According to Stigler, purchasers will be willing to search for more information on price and

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usage of the term "multisource" which differs from the more common concept. Here "multisource" refers to various brands in the same therapeutic class, whereas multisource more commonly refers to both branded and generic versions of an identical molecular entity. Also, at the time this analysts' report was written, Viagra was the only member in the class of erectile dysfunction drugs. Since then, Cialis and Levitra have entered.

[197] George J. Stigler, "The Economics of Information", *Journal of Political Economy*, 69:3, June 1961, pp. 213-225.

quality as long as the expected incremental benefits from search exceeded expected incremental costs. Sellers understand this, and act appropriately. In the current context, when there is only one effective drug available in a therapeutic class, very little if any search or discounting will take place. When, however, several competing patent-protected drugs are available in a therapeutic class that under appropriate medical conditions can be substituted one for another, PBMs and third party payors face incentives to search for price discounts and rebates. In such a situation, will an oligopolist grant discounts, or will each steadfastly refuse to do so?

147. In a subsequent article entitled "A Theory of Oligopoly", published in 1964, Stigler examined the conditions under which an oligopolist would be willing to engage in discounting.[198] While explicit or even implicit collusion among oligopolistic sellers would be illegal, each manufacturer nonetheless would prefer that others not "cave in" to demands for discounts. As long as there is little possibility of being detected, however, it will typically be profitable for the manufacturer to grant a secret discount, particularly to a large buyer who can move market share. Detection of the discount becomes particularly difficult when it takes the indirect form of modifying some non-price dimension of the transaction. If manufacturers have reason to believe *ex ante*, however, that a potential purchaser is likely to report publicly and truthfully the "secret" prices tendered to it, the manufacturers are less likely to offer "secret" discounts in the first place.

148. Health economics textbook authors have considered implications of Stigler's notions of the economics of information for health care markets. Paul J. Feldstein, for example, in a section of his *Health Care Economics* textbook under the heading "Lack of Consumer Information" writes as follows:

[198] George J. Stigler, "A Theory of Oligopoly", *Journal of Political Economy*, 72:1, February 1964, pp. 44-61.

> "It is important to keep in mind that since information is costly to gather, rational consumers are unlikely to become completely knowledgeable; they will gather information to the point where the marginal benefit of additional information equals the marginal cost of collecting it. For some types of medical services, the marginal benefit of additional information will be very high; for others, there will be little advantage to investing a great deal in the search process.
>
> Similarly, for price, product and quality competition to occur, it is not necessary that all consumers be informed. There are few, if any, markets where all purchasers are well informed. Lack of information by the majority of purchasers or even by the average purchaser does not preclude price competition from occurring. As long as the marginal purchaser is informed and price sensitive, demand curves have negative slopes, and providing competition for these purchasers is what makes competitive markets work."[199]

B. 3. b Price Transparency with Competing Oligopolists/Monopolists: Evidence

149. In terms of empirical support, Stigler [1964] provided only limited empirical evidence consistent with his theory of oligopoly pricing, namely, the less perfect the market knowledge (measured by the greater variance in transactions prices), the more extensive on average was the price-cutting off quoted or listed prices.

150. Because of the inherent difficulties in observing secret price dealing, it has proven difficult for researchers to obtain and report reliable and complete data on secret vs. non-secret discounts, along with their longer-term economic impacts on prices paid by consumers. There is, however, a small body of experimental research in economics that that provides evidence on secret discounting. Here a well-known study is that by Professors Douglas Davis and Charles Holt, who show that when transactions prices must be posted, potentially colluding firms in the laboratory maintained near-monopoly prices. However, when the possibility of offering secret discounts was introduced, laboratory sellers found sustaining implicit collusive agreements much

[199] Paul J. Feldstein, *Health Care Economics*, 4th Edition, Albany, New York: Delmar Publishers Inc., 1993, p. 327.

more difficult, and in such situations transactions prices tended to fall toward competitive levels, thereby benefiting consumers.[200]

151. Turning to the real world, rather than the worlds of economic theory, economics textbooks and experimental economics, I note that participants in and observers of the pharmaceutical marketplace have offered their own judgments on the applicability of the Stiglerian view that "the best deals are secret deals".

152. For example, Anthony Barrueta, Chief Counsel for Kaiser Foundation Health Plan, a staff model health maintenance organization, is quite clear concerning the desirability of confidential rather than transparent prices:

> "It is important and sensible that in their contractual relationships, PBMs and their employer/payer customers share adequate information to assure that the PBM is acting in the customer's best interest. However, in what is fundamentally an oligopoly prescription drug market, it is equally important to maximize market competition among drug manufacturers. We believe that price competition can best be achieved when negotiated prices and rebates are kept confidential. Widespread public disclosure of prices is unnecessary to assure that the ultimate payer receives most of the benefit of drug rebate agreements. Auditors operating under strict confidentiality agreements can assure that rebates are shared properly while maintaining confidentiality of prices. More expansive disclosure would ultimately result in fewer discounts and rebates, exacerbating the existing drug cost crisis."
>
> "…We believe there is a significant risk that overregulation of PBMs, particularly in terms of indiscreet disclosure of negotiated discount and rebate arrangements, has the potential to undermine the ability of PBMs to be able to continue to negotiate prices effectively with manufacturers."[201]

153. Similar views appear in the Mathematica study prepared for the Henry J. Kaiser Family Foundation. Noting that rebates are highly confidential, particularly when they are steep, the Mathematica study authors stated:

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[200] Douglas D. Davis and Charles A. Holt, "Conspiracies and Secret Discounts in Laboratory Markets", *The Economic Journal*, 108, May 1998, pp. 736-756.
[201] Baruetta, *supra*, pp. 2-3.

> "PBMs guard this information closely, as do manufacturers. Having the rebate levels revealed in the transaction price might discourage manufacturers from offering steep discounts."[202]

154. That requiring prices to be fully transparent may in some cases hinder rather than foster price competition has been noted by the Federal Trade Commission in other contexts. For example, appearing in 1996 before the Commonwealth of Massachusetts Alcoholic Beverages Control Commission, Phoebe Morse, Director of the Boston Regional Office of the Federal Trade Commission, urged repeal of price posting regulations that require wholesalers of alcoholic beverages to post prices on a monthly basis and to adhere to those posted prices in their sales to retailers the following month. Stating that "We believe that repeal of the price posting regulations would increase competition", the FTC Regional Director went on to cite Stigler's 1964 Theory of Oligopoly article explicitly, and relate its conclusion of anticompetitive price transparency to the repeal of required price posting: "The availability of comprehensive price information tends to make it easier for industry members to coordinate prices tacitly and to detect and discourage deviation from the consensus price."[203] A footnote at the end of this quotation provided additional explanation, implicitly contrasting the retail brand licquor market setting with the "fully competitive" market paradigm:

> "In fully competitive markets, the provision of quick, accurate information generally tends to be pro-competitive. Indeed, perfect information is one of the underlying assumptions of the competitive model. But certain markets may not fit the competitive model well even in the absence of price regulation or price posting. They may be conducive to collusion because concentration is high in some segments or because entry is restricted by statute. In such markets, greater information can lead to the results described in the text."[204]

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[202] Henry J. Kaiser Family Foundation, *The Role of PBMs in Managing Drug Costs: Implications for a Medicare Drug Benefit*, Prepared by Mathematica Policy Research, Inc., January 2000, p. 50. Available online at www.pharmacy.ca.gov/publications/pbm_kff_role.pdf, last accessed 1/28/05.

[203] Statement of Phoebe Morse, Director, Boston Regional Office, Federal Trade Commission, to the Commonwealth of Massachusetts, Alcoholic Beverages Control Commission, June 26, 1996, pp. 1, 3. Available online at http://www.ftc.gov/os/1996/06/morse_st.pdf, last accessed January 27, 2005.

[204] Statement of Phoebe Morse [1996], *supra*, p. 3, fn. 6.

155. Many industrial organization economists are sympathetic with the view that in the context of competing oligopolists/monopolists, extensive price transparency is not necessarily beneficial because "the best deal is likely a secret deal". That view, however, is not universally shared, as the current litigation has demonstrated. Supporting arguments of the "beneficial price transparency" view, however, often implicitly invoke the full competition paradigm, which in my assessment is inappropriate as a characterization of transactions involving PBMs and manufacturers of branded single-source drugs. Attorney David Balto, for example, testifying at the same FTC hearings as Mr. Baruetta, argued that greater price transparency involving PBM rebates would assure competition by giving consumers bargaining power, "decrease prices by requiring PBMs to disclose price concessions and rebates from pharmaceutical manufacturers", so that "armed with information about rebates, buyers can encourage PBMs to compete to secure lower prices".[205] In a subsequent publication, Balto argued that before Congress extends the use of PBMs in a Medicare pharmaceutical benefit, "it must reform PBM markets to provide substantially greater transparency".[206]

B. 4. Contracts Between PBMs and Health Plans/Insurers: Rebate Transparency

156. Earlier I noted that it was useful to distinguish three sets of contracts that dealt with PBM transparency issues. To this point the discussion has centered on contracts between manufacturers and PBMs. A different set of contracts is that between PBMs and third party payors such as health plans and insurers, in which issues of disclosure of the manufacturer-PBM contract terms (the first set of contracts) can become an issue.

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[205] David A. Balto, "Pharmaceutical Benefit Managers: Competition and Transparency", FTC Healthcare Hearings, 6/26/03, accessed at www.ftc.gov/ogc/healthcarehearings/docs/030626balto.pdf. According to Plaintiffs' Expert Dr. Raymond S. Hartman, David A. Balto is the former Policy Director of the Bureau of Competition of the Federal Trade Commission. See *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, supra, December 16, 2004, p. 73.

[206] David A. Balto, "Competitive Concerns and Price Transparency in the PBM Market", Update, Food and Drug Law Institute, September/October 2003, Powerpoint presentation, slide #11. Online at www.rkmc.com/pdf/price_transparency.pdf.

157. To a considerable extent, the degree of transparency between an individual PBM and a third party payer regarding rebates, as well as the extent to which they are passed through to the third party payors, is negotiable, as are audit rights. Examples of publicly available information regarding aspects of rebate transparency come from a variety of sources.

158. Banc of America industry analysts, for example, described the process in 2002 as follows:

> "A large percentage of the manufacturer rebates (we estimate an average of 70%) is passed on to the PBM client (the payor). This percentage varies a great deal, ranging from 0% to 100%, depending on the other components of the contract between the PBM and client. In other words, the PBM will get paid a fair amount for its services, one way or another – some clients would rather receive 100% of the rebate and pay higher administrative fees and/or get a lower share of pharmacy discounts, while others receive none of the rebates but pay much lower administrative fees and/or get a much higher share of pharmacy discounts".[207]

159. One reason health plans/insurers differ in their intensity to desire rebates vs. pharmacy discounts when negotiating with PBMs stems from the fact that if rebates are to be shared, the sizes of rebates are unknown *ex ante*, but are instead only revealed *ex post* after the health plans/insurers actual adjudicated volume claims and shares are calculated to assess whether targets had been attained, triggering the rebates. To the extent health plans/insurers differ in their willingness to take on risk, they will likely vary in their preference between unknown rebate amounts and more predictable discounts, with the more risk averse plans/insurers preferring the less risky discounts off AWP instead of uncertain rebate amounts.

160. Further discussion and information concerning rebates, audit rights, the bidding process and other subjects typically addressed when negotiating contracts between payors and PBMs, was presented at FTC public hearings in June 2003, and is also outlined in the joint

[207] Banc of America Securities, Equity Research United States, *Pharmacy Benefit Managers: Keeping a Lid o n Drug Costs*", Health Care Technology and Distribution Industry Overview, February 2002, p. 21.

FTC/DOJ report issued in 2004.[208] An earlier 2000 Report to the President by the Department of Health & Human Services stated that:

> "Industry sources report that the insurer or employer typically receives 70 to 90 percent of the rebates. In addition, the PBM will often guarantee a minimum per-prescription rebate, in case actual rebates received from manufacturers are lower than expected. While estimates differ, industry experts report that the value of rebates passed on to insurers or employers may average about $1.00 per claim."[209]

161. In discussing third party payor PBM benefit portfolio choices that were increasing in number and complexity, benefit consultants such as Pam Bertranb from Towers Perrin wrote already back in 1994, advising that "Clients should want to see the whole pool of rebate money and take a negotiated rate out of that, or ask for a higher guarantee".[210] Writing several years later in a different trade journal, health plan consultants John Tripodi and Paul McDonough of Health Information Systems, Inc., exhorted third party payors to conduct audits, stating:

> "One way to reduce risk is for an HMO, employer or indemnity payer to conduct an audit of their PBM. Although this may seem like a logical business procedure, in fact, audits have only recently become popular as payers seek new ways to control costs….A PBM audit may not happen without resistance, and there are several issues that a plan will need to address. First is the question of whether the plan has the legal right to perform an audit. Even if the current contract does not include audit rights, a PBM may cooperate to maintain positive relations for contract renewal. In the event that audit rights are not in the current contract and the PBM is not receptive, the plan should negotiate their inclusion in all future contracts."[211]

[208] See, for example, the powerpoint presentation of John Richardson, The Health Strategies Consultancy, LLC, "PBMs: The Basics and an Industry Overview", particularly slide #25, "Manufacturer Rebates". Online at www.ftc.gov/ogc/healthcarehearings/docs/030626richardson.pdf , accessed 12/31/04; also see *Improving Health Care: A Dose of Competition, A Report by the Federal Trade Commission and the Department of Justice*, July 2004, ch. 7, "Industry Snapshot and Competition Law: Pharmaceuticals", pp. 15-18

[209] Report to the President: Prescription Drug Coverage, Spending, Utilization, and Prices, Department of Health and Human Services, April 2000, pp. 105-106.

[210] Quoted by Jeannie Mandelker, "Get The Most Out of Your PBM", *Business and Health*, November 1994, p. 40.

[211] John Tripodi and Paul McDonough, "Auditing Your PBM", *Prescription Price Watch*, March 1997, pp. 1,4.

Detailed discussions and advice concerning when to conduct a PBM audit, how to plan for it, and how to carry it out, including rebate audits, have long been easily found in widely available industry trade publications.[212]

162. Two other FTC-related matters regarding PBM price transparency merit brief discussion. First, after conducting public hearings and considering evidence brought to its attention, as well as information gained from various investigations, the FTC has taken a strong position believing that competition among PBMs is sufficient to ensure that decision-makers have sufficient information at their disposal to make wise choices that can benefit consumers. Notably, the FTC envisages a market-generated *optimal* amount of transparency as being the goal of policy, rather than a regulatory-imposed amount of transparency:

> "Vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms. Vigorous competition is also more likely to help ensure that gains from cost savings are passed on to consumers of health care services, either as lower premiums for health insurance, lower out-of-pocket costs (for that portion of health care expenditures borne directly by consumers through deductibles and co-payments), or improved services. Negotiated limitations on transparency are unlikely to be so severe that health plan sponsors cannot assess the price and quality of the services they are receiving. Just as competitive forces encourage PBMs to offer their best price and service combination to health plan sponsors to gain access to subscribers, competition also encourages disclosure of the information health plan sponsors require to decide on the PBM with which to contract."[213]

163. In related state (rather than federal) legislative proposals entailing increased risk of public disclosure of detailed PBM-manufacturer rebate provisions by third party payors, the

[212] See, for example, Susan Peard and Kevin Johnson, "Taking stock of your PBM", *Business & Health*, March 2000, pp. 43-47.
[213] *Improving Health Care: A Dose of Competition, A Report by the Federal Trade Commission and the Department of Justice,* July 2004, ch. 7, "Industry Snapshot and Competition Law: Pharmaceuticals", p. 17.

FTC has reinforced the conclusion that mandated increased cost transparency is likely to increase rather than decrease consumers' prices.[214]

164. Other governmental agencies have agreed with the FTC on this issue. For example, in the process of estimating the likely costs of a Medicare Part D drug benefit for the elderly under proposed provisional amendments significantly increasing the risk of public disclosure of manufacturer-PBM pricing details, the Congressional Budget Office concluded:

> "Consequently, PBMs operating as part of the Medicare prescription drug plan would find it more difficult to obtain significant price concessions and rebates from drug manufacturers, who would be concerned that the terms of those favorable deals could be determined by competitors or other purchasers. Consequently, CBO estimates that, with this amendment, the degree of drug-cost management under S. 1 would decline and would no longer exceed the levels of cost management seen in the current employer market…As a result, CBO estimates that section 133 would increase the estimated costs of S. 1 over the 2004-2013 period by $40 billion."[215]

165. Finally, in part because the PBM industry was already quite highly concentrated prior to the proposed acquisition of Advance PCS by Caremark in September 2003, the FTC undertook an investigation assessing likely competitive impacts of this merger between two of the largest PBMs, thereby placing the PBM industry again under close regulatory scrutiny.[216] In announcing that it was closing its investigation of the proposed acquisition and allowing the

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[214] See, for example FTC press release, "FTC Staff: California Bill May Raise Prices for Pharmaceuticals", online at http://www.ftc.gov/opa/2004/09/capbm.htm, accessed 1/15/2005; FTC press release, "FTC Staff: Rhode Island Bills Would Raise Prices for Pharmaceuticals", online at http://www.ftc.gov/opa/2004/04/ribills.htm, accessed 1/16/2005. In both cases, texts of the full letters can be obtained via the FTC website.

[215] Congressional Budget Office Cost Estimate, H.R. 1, Medicare Prescription Drug and Modernization Act of 2003, as passed by the House of Representatives on June 27, 2003, and S. 1, Prescription Drug and Medicare Improvement Act of 2003, as passed by the Senate on June 27, 2003, with a modification requested by Senate conferees, July 22, 2003, pp. 10-11. Online at http://www.cbo.gov/showdoc.cfm?index=4468&sequence=0, last accessed 1/26/05.

[216] Noting that the DOJ's horizontal merger guidelines classified a market as "highly concentrated" if its Herfindahl-Hirschman Index ("HHI") has a value of 1800, and as possibly raising DOJ/FTC concerns if the merger increases the HHI by more than 100 points, Goldman Sachs industry analysts reported that the pre-merger HHI was 2132 if the market were defined to include the various "captive" PBMs as a single firm, and 2708 if the market definition excluded captive PBMs entirely. Post-merger, the HHIs would increase by 243 and 345 points, respectively, to 3093 (excluding captive PBMs) and 3275 (including captive PBMs as a single PBM). See Goldman Sachs Global Equity Research, *Healthcare: Supply Chain – Pharmacy Benefit Managers, United States,* October 16, 2003, pp. 56-57.

Caremark/AdvancePCS acquisition to proceed,[217] the FTC noted that small employers would continue to be provided services by small, often regionally-oriented PBMs, post-acquisition, and that:

> "… large employers are not likely to encounter anticompetitive effects from the acquisition in light of the competition that will exist following this transaction. Competition from the remaining independent, full-service PBMs with national scope – Medco, Express Scripts and the merged Caremark/AdvancePCS – and significant additional competition from several health plans and several retail pharmacy chains offering PBM services should suffice to prevent this acquisition from giving rise to a potentially anticompetitive price increase….
>
> At most, the acquisition is likely to increase the bargaining power of the merged PBM and to increase its shares (and correspondingly reduce the pharmacies' shares) of the gains flowing from contracts between the PBM and the pharmacies. It is likely that some of the PBM's increased shares would be passed through to PBM clients. Although retail pharmacies might be concerned about this outcome, a reduction in dispensing fees following the merger could benefit consumers."[218]

A footnote to this last paragraph added: "We anticipate that competition among PBMs will remain vigorous in the wake of the Caremark/AdvancePCS acquisition, and that this competition is likely to cause PBMs to pass on at least some of their cost savings to their customers in order to gain or retain their business."[219] Of particular note here is that in the first paragraph of the above quotation from the FTC, the FTC appears to acknowledge the competitive benefits and information flow aspects deriving from the highly diversified ownership of PBMs.

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[217] The Goldman Sachs industry observers compared this acquisition and its effects on competition to that of two large wholesalers, whose merger was also investigated and approved by the FTC. See Goldman Sachs Global Equity Research, *Healthcare: Supply Chain – Pharmacy Benefit Managers, United States,* October 16, 2003, pp. 56-57. Concentration and industry structure of the pharmaceutical wholesaler markets is discussed in Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Introduction Final Report, Contract #500-00-0049, Task Order 1, Cambridge MA: Abt Associates, Inc., August 30, 2004, pp. 10-11.

[218] Statement of the Federal Trade Commission, In the Matter of Caremark Rx, Inc./AdvancePCS, File No. 031 0239, pp. 2-3, February 11, 2004. Online at www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf, last accessed 01/16/05.

[219] Footnote 6, Statement of the Federal Trade Commission, In the Matter of Caremark Rx, Inc./Advance PCS, *supra*, p. 3.

166. In summary, because a very substantial proportion of transactions between manufacturers and PBMs involves patent-protected drugs competing with one another (in the "competing monopoly/oligopoly stage"), discounts and rebates from manufacturers to PBMs are likely to occur only if these price concessions are reasonably confidential, and even when verified by negotiated audits, are unlikely to be made public. There is a long tradition in economics suggesting that in such environments, "the best deals are secret deals". Third party payors have argued against increased price and rebate transparency. The FTC and DOJ have examined price and rebate transparency issues at considerable length, and have concluded that the structure of the PBM industry, and in particular its diverse ownership, facilitates vigorous competition. Indeed, within the last year the FTC has approved an acquisition involving two of the largest PBMs, noting that even after this acquisition, it expected competition to be vigorous, and rebates to be shared with third party payors.

C. Information with Vertically Integrated Mail Order Firms and PBMs

167. In sub-section A of Section III I examined information issues involving vertical integration between drug manufacturers and PBMs, while in the previous sub-section B I examined information issues and competition among various PBMs, including issues of rebate transparency and horizontal integration, both in the context of branded self-administered drugs. I now examine brand-generic issues raised by Plaintiffs regarding vertically integrated mail order firms and PBMs.

168. An issue that has figured quite prominently in debates leading up to passage of the Medicare Modernization Act of 2003, and more recently in various state legislatures, is the extent to which PBMs owning mail order services switch prescriptions from generics to brands, thereby perhaps increasing their rebates even as they secretly passed on to their insurer/third

party payor clients the higher costs of the branded drugs. This policy, dubbed "self-dealing", would not be sustainable if competition among PBMs were effective, for once discovered or suspected, PBM clients would shift to other PBMs that did not engage in such cost-increasing practices.[220] In the following paragraphs, I summarize and evaluate the available evidence addressing Plaintiffs' contention that self-dealing by vertically integrated mail order firms and PBMs has likely harmed the third party payor class. I also note forthcoming evidence on this issue that is scheduled for release by the FTC in June 2005.

169. Plaintiffs' Expert Dr. Raymond Hartman cites an "academic analysis" by Drs. James Langenfeld and Robert Maness finding "that the impact of competition among PBMs is insufficient to eliminate 'self-dealing' practices that increase the cost of pharmaceuticals."[221] I begin by summarizing and critiquing that apparently still unpublished study.

> In the Executive Summary accompanying their report, Langenfeld and Maness state:
>
> "One way in which PBMs with captive mail order houses can increase sales of single source drugs is through therapeutic switching. Because it can take several days to fill a mail order prescription, mail order dispensing provides time for PBMs to obtain the necessary physician permission to switch prescriptions to single source alternatives. We find that such switching occurs more frequently in captive mail order houses than unaffiliated mail order houses, as evidenced by generic utilization being much less at captive mail order houses than at mail order houses that are unaffiliated with a PBM. Based on the best available evidence, captive mail order has a generic utilization of only 29.4 percent while independent mail order has a generic utilization rate of 38.9 percent."[222]

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[220] See *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, supra, p. 15. Issues concerning the extent of competition in the PBM industry are addressed in the *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, in the two pages prior to and then in Section C, Commercial Insurance Coverage and Reimbursement for Self-administered Brand Name Drugs, pp. 34 – 49. Dr. Hartman responds to Mr. Young in *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, Section VI, pp. 72-82.

[221] Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification, September 3, 2004, *supra,* Attachment C, fn. 30, and other text on p. 10. The study cited is by James Langenfeld and Robert Maness, "The Cost of PBM 'Self-Dealing' Under a Medicare Prescription Drug Benefit", dated September 9, 2003. Langenfeld and Maness are both associated with LECG, a well-known economic consulting firm.

[222] Langenfeld and Maness [2003], *supra*, p. 1.

Note that the evidence Langenfeld-Maness cite as supporting their contention that therapeutic switching occurs is their finding here that generic utilization is much less at captive mail order houses than at mail order houses unaffiliated with a PBM. Based on this alleged generic utilization differential, they then estimate the cost impact of the alleged self-dealing involving therapeutic switching. It is useful to begin with some definitions.

170. The generic utilization rate is computed as the proportion of all prescription claims for all drugs – regardless of whether they have generic equivalents -- that are dispensed as generics. Another measure of substitution between generic and brand is based on just those molecules having both brand and generic versions available on the market, and that involves the calculation of the proportion of brand plus generic prescriptions for the identical molecule that are dispensed as generics; this is what industry observers frequently call the "generic substitution" rate, although Langenfeld and Maness and others have used the terms "generic utilization" and "generic substitution" rates interchangeably, along with the "generic dispensing" rate.[223] I note that in the above definition of generic substitution (i.e., the proportion of brand plus generic prescriptions for the identical molecule that are dispensed as generics), any "self-dealing" involving *between-molecule* therapeutic switching would not be captured.

171. Although details on their data sources are sketchy, Langenfeld and Maness apparently use aggregate mail order data as their measure of captive retail, stating "The best available proxy for captive retail is the figure for all mail order, since 77% of mail order sales are made from captive mail order divisions."[224] Regarding the source of data for unaffiliated mail

[223] See, for example, Langenfeld and Maness [2003], *supra*, p. 1 ("generic utilization rate"), p. 6 ("generic substitution rate") and p. 7, Figure 1 ("generic dispensing rate").
[224] Langenfeld and Maness [2003], *supra*, p. 6.

order, the only information that is given is a note to Figure 1, "Unaffiliated mail order estimates based on conversations with retail chains".[225]

172. Individuals receiving their drugs through mail order dispensing rather than from traditional retail pharmacies may differ significantly from one another, particularly in their utilization of long-term maintenance drugs treating chronic conditions (drugs more likely dispensed from mail order) versus drugs required for unexpected acute conditions and exacerbations (more likely dispensed from retail pharmacies on an as-needed basis). The generic share dispensed by retail pharmacies is also affected by the fact that among prescriptions dispensed for acute conditions at retail pharmacies, antibiotics are common, and an unusually large proportion of antibiotics are available in generic form.[226] This raises issues concerning how one should account for the differential mix of therapies treated by prescription drugs dispensed at retail vs. mail order pharmacies when comparing overall generic substitution rates.

173. Acknowledging that mail order prescriptions are particularly appealing for those individuals having long-term chronic conditions, Langenfeld and Maness attempt to control for such differential "mix" issues (apparently unsuccessfully, it turns out) by limiting their analysis to the ten therapeutic categories most dispensed through mail order within the ten largest cities. Data source details are again sketchy; a note to Figure 2, entitled simply "Various Generic Rates for Mail Order vs Retail: 2002", states: "Source: Compiled by PRIME Institute, University of Minnesota from data provided by CVS Pharmacy based on IMS Health data for same mix of drugs drwn [sic] from 10 most frequently dispensed therapeutic categories of drugs in mail order

[225] Langenfeld and Maness [2003], *supra*, Note to Figure 1, p.7.
[226] *Takeda and Lilly Prescription Drug Benefit Cost and Plan Design Survey Report,* 2001 Edition, Tempe AZ: The Pharmacy Benefit Management Institute, Inc., p. 27.

pharmacy from August 2001 to July 2002".[227] Hence, whether the data are just for CVS' sales or are national IMS Health data provided via CVS, is unclear; also unspecified is whether the averages are weighted or unweighted means. In any case, Langenfeld and Maness report their findings and their interpretation of them as follows:

> "The average generic substitution rate for mail order in these ten cities is 32.2 percent. The average retail generic substitution rate is 38%. Thus, the difference on average is 5.8%. This demonstrates that the mix is unlikely to account for the significant difference in substitution rates, and it is consistent with opportunistic self-dealing by PBMs dispensing drugs through their mail order divisions."[228]

174. When Langenfeld and Maness go a step further and exclude all single source drugs from the apparently same data set, thereby confining their analysis just to drugs that have multiple sources (brand and generic), they find that the average generic substitution rate for captive mail order in the ten cities is about 78%, slightly less than the 81% average for unaffiliated mail order (which they now call "non-captive mail order (as measured by its proxy)").[229] Although they report no statistical tests of significance, they conclude: "These data support the conclusion that differences in the mix do not explain the low level of generic utilization by PBM-owned mail order operations."[230]

175. Finally, based on "data from IMS Health for all products in a single category of drugs – cardiovascular products" (although whether this is just for CVS, or for a much larger retail sample, and whether for just ten cities or overall national retail, is unclear), Langenfeld and Maness report that the percentage of prescriptions "filled generically through mail order (the proxy for captive mail order)" was less than that for "retail (the proxy for independent mail

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[227] Langenfeld and Maness [2003], *supra*, Figure 2, p. 8. A footnote 16 on the same page adds: "The ten drug categories included in this analysis are adrenergic blockers, systemic antiarthritics (including NSAIDS), antidepressants, anti-ulcerants, calcium blockers, cholesterol reducers, oral diabetes products, non-injectable diuretics, renin angiotensin antagonists, and sex hormones."
[228] Langenfeld and Maness [2003], *supra*, p. 8.
[229] Langenfeld and Maness [2003], *supra*, p. 9.
[230] Langenfeld and Maness [2003], *supra*, p. 9.

order)": in 2001, the difference is 4.6 percentage points (34.6% for mail order vs. 39.2% for retail), while in 2002 the difference is 6.3% (36.0% for mail order vs. 42.3% for retail).[231]

176. In my judgment, the Langenfeld-Maness analysis is seriously deficient due to its lack of details concerning data sources, and its methodology that does not take into account sufficiently the implications of "mix" differentials between mail order and retail customer demand. While Plaintiffs' Expert Dr. Hartman characterizes it as an "academic analysis"[232], and although it is my understanding that over the years both Drs. Langenfeld and Maness have held adjunct academic appointments, to the best of my knowledge, the Langenfeld-Maness analysis has not been published in any peer-reviewed professional or academic journal, nor has it even been issued as an academic working paper, a traditional outlet for "academic analysis".[233] Perhaps it is for these reasons that in summarizing the Langenfeld-Maness findings, Dr. Hartman comments in the last line of a footnote that "It should be noted that these conclusions are subject to ongoing empirical analysis."[234]

177. Not surprisingly, the Pharmaceutical Care Management Association, a national trade association representing PBMs in the US, disagrees with the Langenfeld-Maness analysis

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[231] Langenfeld and Maness [2003], *supra*, Figure 4, p. 10, and text, p. 10.

[232] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, *supra,* Attachment C, p. 10, fn. 30.

[233] When the LECG website was visited to examine the professional biography of Dr. Robert S. Maness, his curriculum vita was found, apparently last revised 10/05/04, which reports employment at LECG, LLC, from June 1996 to the present, and Director, 2004 to the present. From 2000-2003, the curriculum vita reports that he was Adjunct Associate Professor at Texas A&M University, College Station, Texas. In the section of his curriculum vitae entitled "Papers and Publications" (p. 6), the following appears: "The Cost of PBM 'Self-Dealing' Under a Medicare Prescription Drug Benefit," with James Langenfeld, September 9, 2003**."** The LECG website also contains a biography of Dr. James A. Langenfeld, with the January 27, 2004 date on the last page (p. 11). The curriculum vita states that since August 1996 , he has been Director of LECG, LLC, and that from August 2002 to the present, he has been an Adjunct Professor at Loyola University Chicago, School of Law. In the section of his curriculum vita entitled "Papers and Publications", the following is listed as the second item: ""The Cost of PBM "Self-Dealing" Under a Medicare Prescription Drug Benefit", (with Robert Maness), September 2003." See www.lecg.com/website/lwbios.nsf/OpenPage/JamesLangenfeld/$FILE/Langenfeld.pdf, accessed January 24, 2005. Neither web search revealed distribution of this paper as an academic-issued working paper, nor as forthcoming in a peer-reviewed journal.

[234] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, *supra,* Attachment C, p. 9, fn. 24.

and its findings, claiming not only that it was "bankrolled by three of the nation's largest retail pharmacies", but also calling it "an eleventh-hour, rent-a-study, which directly contradicts independent government data".[235]

178. Recently, however, a peer-reviewed study has been published in a well-known health policy journal, *Health Affairs*, reporting findings that contradict those of Langenfeld and Maness concerning the interpretation of differential generic utilization rates by mail order vs. retail pharmacies.[236] The authors, Marta Wosinska and Robert S. Huckman, both on the faculty at Harvard Business School, begin by noting that use of the aggregate generic-dispensing rate (what Langenfeld and Maness also called the generic utilization rate) is problematic because it confounds brand-generic variation in the performance of the dispensing entities with variations in the composition of their clients demanding various prescription drugs (the "mix" issue).

179. To address issues of customer heterogeneity, Wosinska-Huckman utilize the universe of data from five large integrated PBMs having both retail and mail order pharmacy benefits, implying that the cohort of enrollees is the same when retail and mail order claims are compared.[237] In the retail sector, the top ten six-digit Generic Product Identifier classes

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[235] PCMA: Retail Pharmacy-Funded "Study" on PBMs Runs Afoul of Government Findings on PBM Cost-Savings, online at http://www.pcmanet.org/2004_addReleases/ReleasePrint/release40_print.html, accessed 1/22/2005. One "independent government data" study to which this press release apparently refers is that by the US General Accounting Office. While that study showed that prescription drugs (both branded and generic) received by beneficiaries through mail order pharmacies were on average less costly than those purchased by consumers paying cash at retail pharmacies, notably the study did not compare prices at captive mail order vs. unaffiliated mail order studies, as Langenfeld and Maness attempted to do. See *United States General Accounting Office, Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*, Report to the Honorable Byron L. Dorgan, U.S. Senate, GAO-03-196, January 2003. Available at www.gao.gov/cgi-bin/getrpt?GAO-03-196.

[236] Marta Wosinska and Robert S. Huckman, "Generic Dispensing And Substitution In Mail and Retail Pharmacies", *Health Affairs – Web Exclusive*, W4-409 to W4-416, posted 28 July 2004. Available online at www.healthaffairs.org. An abstract of the article was published in the hardcopy edition of *Health Affairs*, 23(5), September/October 2004, p. 284.

[237] The five PBMs are AdvancePCS, Caremark, Express Scripts, Medco and Prescription Services. The data exclude Medicaid and unfunded business, are national in scope, and cover the first six months of 2003. These data also include brand and generic over-the-counter medications that are covered by several plans, which I understand are not at issue in this litigation. See Wosinska and Huckman [2004], *supra*, pp. W4-410 and W4-411, and fn. 6 on p. W4-416.

accounted for 28.34% of claims, but in the mail order sector they accounted for a larger 40.89% of claims, implying that the therapeutic mix of drugs is more concentrated in mail order than in retail, or alternatively, that the drugs dispensed in retail come from more diverse therapeutic classes than those dispensed via mail order. Over all drug categories, when computing an aggregate generic dispensing rate (the proportion of all prescription claims filled by generic drugs, including molecules for which no generic was on the market), Wosinska-Huckman report a 48.51% share for retail and a 38.79% proportion for mail order, implying a differential of 9.72%, very close to the 9.5% differential reported by Langenfeld-Maness; however, these Wosinska-Huckman percentage *levels* of generic dispensing rates are about ten percentage points higher than those in Langenfeld-Maness, both for what the latter reported for unaffiliated mail order (38.9%) and for captive mail order (29.4%).[238]

180. To control for differences across therapeutic areas, Wosinska-Huckman first apply the same therapeutic mix to both retail and mail pharmacies (using mail six-digit weights in both the retail and mail channels, but employing channel-specific generic dispensing rates in each six-digit class), thereby creating what they called "normalized generic-dispensing rates". Using just this mix correction, Wosinska-Huckman reduced the aggregate generic dispensing rate differential of 9.72 points to 1.26 points (from 48.51% to 40.05% for retail, with mail unchanged at 38.79%), implying that "87 percent of the difference in the aggregate generic dispensing rates (more than 8.4 percentage points) can be explained by differences in therapeutic mix across channels."[239]

181. Next Wosinska-Huckman computed what they call the aggregate generic substitution rate, which for those molecules having both brand and generic versions, is the

[238] Wosinska-Huckman [2004], *supra*, Exhibit 4, p. W4-414; Langenfeld-Maness [2003], *supra*, Figure 1, p. 7. Recall my earlier comments on proxies used by Langenfeld-Maness for unaffiliated and captive mail order.
[239] Wosinska-Huckman [2004[, *supra*, p. W4-413, and Exhibit 4, p. W4-414.

proportion of claims dispensed as generics. In large part because of state mandatory substitution provisions, this aggregate generic substitution rate is very high for both channels – for mail order it is 92.99%, slightly greater (0.19 percentage points) than at retail where it is 92.80%.[240] Finally, when the authors normalize the aggregate generic substitution rate for the retail channel by using the mail channel mix of molecules, this difference increases slightly to 0.97 percentage points, 92.02% for retail (down from 92.80%), while mail remains the same at 92.99%.[241]

182. Wosinska-Huckman conclude by summarizing their most important finding and its implications:

> "The fact that mail order pharmacies have lower generic-dispensing rates than their retail counterparts has been used as evidence of self-dealing that could arise when a PBM is both a plan administrator and a pharmacy owner. Our analysis found that the difference in aggregate generic-dispensing rates between mail and retail pharmacies confounds variation in performance with differences in demand. Using the universe of claims for third party clients of five large PBMs, we found that 87 percent of the difference in the aggregate generic-dispensing rate is driven by differences in therapeutic mix…. These results underscore the fact that it is impossible to make definitive judgments about pharmacy performance based on the generic-dispensing measure. As a result, addressing the proposed conflict of interest ultimately requires direct analysis of whether the monetary benefits from rebates outweigh the cost of interventions for therapeutic substitution and the obligations PBMs have to their clients."[242]

183. While the evidence presented in the peer-reviewed article by Wosinska-Huckman is in my judgment quite compelling, and not subject to some of the obvious problems in the unpublished paper by Langenfeld-Maness, a definitive conclusion concerning the extent of PBM self-dealing and its cost implications awaits the publication of others' research. For the moment,

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[240] Wosinska-Huckman attribute this unexpected finding, which runs contrary to the self-dealing conflict of interest argument, as reflecting the fact that although states' mandatory generic substitution provisions require the pharmacist to substitute the generic for brand unless the physician states "dispense as written", because mail order pharmacies typically have several days to fill a mail order prescription, they are more likely than is a retail pharmacist to call a physician who originally wrote "dispense as written" and obtain permission instead to substitute the generic for the brand. This difference, however, while unexpected, is relatively trivial. See Wosinska-Huckman [2004], *supra*, pp. W4-414 to W4-415.

[241] Wosinska-Huckman [2004], *supra*, p. W4-413 and Figure 4, p. W4-414.

[242] Wosinska-Huckman [2004], *supra*, pp. W4-415 to W4-416.

the most convincing evidence of which I am aware is that by Wosinska-Huckman, who report that once one accounts for differences in mix, generic dispensing and substitution rates are essentially the same at mail order vs. retail pharmacies.

184. Thus, Plaintiff's use of findings from an "academic study" regarding apparent differences in mail vs. retail generic substitution rates does not inform controversy in this litigation regarding the extent and cost implications of "conflict of interest" allegations regarding PBMs having integrated mail order operations.

185. Additional publicly available evidence on this "conflict of interest" issue will, however, soon emerge, and may be of assistance to the Court in the near future. A joint report recently issued by the Federal Trade Commission and the Department of Justice states that Section 110 of the Medicare Modernization Act of 2003 requires the Federal Trade Commission to conduct a "conflict of interest" study that includes the following:

> "1. An assessment of the differences in costs incurred by such enrollees and plans for prescription drugs dispensed by mail-order pharmacies owned by PBMs compared to mail-order pharmacies not owned by PBMs and community pharmacies.
> 2. Whether such group health plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees."[243]

The statute requires the FTC to report its findings and any necessary recommendations by June 2005.[244] Apparently stand-alone PBMs, health plan PBMs and retail pharmacy PBMs are providing data to the FTC.[245]

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[243] *Improving Health Care: A Dose of Competition*, Report by the Federal Trade Commission and the Department of Justice, July 2004, p. 18. Available from www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf
[244] Report by the Federal Trade Commission and the Department of Justice [2004], *supra*, p. 18.
[245] See Stephanie Kanwit, Special Counsel, PCMA, "Key Legal Challenges Facing PBMs", presentation given at the 2004 PCMA Annual Meeting, Phoenix, AZ, October 26, 2004. Online at http://pcmaevents.accrisoft.com/clientuploads/Annual_Meeting_2004/Files/KanwitAMMSSlidesfinal.ppt, accessed 1/22/05.

V. COMPETITION, INFORMATION, AND PRICE TRANSPARENCY: PHYSICIAN-ADMINISTERED DRUGS

186. The market environment in which PBMs have managed purchases of self-administered prescription drugs in the last two decades differs markedly from the distribution and management environment that has surrounded physician-administered drug purchases. I have outlined some of the most important differences in Subsection F of Section III of this report. These structural differences have significant implications for the quality of information flows and the nature of competition. A number of characteristics of the market environment for physician-administered drugs contribute to making it more vulnerable to mischief and abuse than is the market for self-administered drugs.

187. First, relative to the market for self-administered drugs, the dollar size of prescription-administered drug sales is very small, even after growing very rapidly in the last five years. In 2002, for example, it is estimated that Medicare paid $8.5 billion for physician-administered drugs, comprising about 3% of total Medicare spending.[246] Adding a 20% coinsurance amount paid by Medicare beneficiaries brings the total to about $10.6 billion.[247] Assuming that non-Medicare purchases of physician-administered drugs are as large as Medicare expenditures (a likely exaggerated assumption) brings the total to $21.2 billion. The entire U.S. prescription drug bill in 2002 was estimated to be about $194 billion.[248] Hence, expenditures on physician-prescribed drugs in 2002 were likely no more than 11% of the total prescription drug

[246] MedPAC [2003], *supra*, p. 154.
[247] One industry observer has estimated that "well over 95%" of beneficiaries receiving organ transplants have Medicare supplemental insurance, Medicaid, or another way to cover the program's 20% coinsurance for immunosuppressant medications. See "Specialty Pharmacies Struggle as Medicare Lowers Payment for Immunosuppressants", reprinted from the June 11, 2004 issue of *Drug Cost Management Report*. Available online at http://www.aishealth.com/DrugCosts/specialty/DCMRPharmaciesStruggleImmunosuppressants.html last accessed 12/29/2004.
[248] IMS Health, "U.S. Purchase Activity by Channel, 2002", available online at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_41551552_41633299,0o.html last accessed 10/25/04.

bill, and a smaller proportion in earlier years, given their substantial recent growth. Taking the total prescription drug market as being between 12% and 15% of overall national health expenditures suggests that in 2002, expenditures on physician-administered drugs were likely less than 1.5% of national health expenditures, and considerably smaller in earlier years. As I have discussed elsewhere,[249] and as stated earlier by the famous nineteenth century economist Alfred Marshall (and reinforced by Nobel Laureate George Stigler's economic theory of information[250]), there is a phenomenon called "the importance of being unimportant" which, in the current context, suggests that other things being equal, it may well be rational for budget managers to focus most of their attention on the larger budget items, and pay little heed to the smaller items. As a proportion of total spending, expenditures on physician-administered drugs have simply not been very important. That makes them more likely not to be on cost cutter's radar screens. As Plaintiff's Expert Dr. Raymond Hartman has stated:

> "While physician-administered drugs have become an increasingly large share of health plan spending in recent years, payers have only just begun to focus on cost control in this segment."[251]

With minimal vigilance, the possibility for unnoticed abuse and mischief is enhanced. Those able to make mischief understand the potential from benign neglect.

188. A second distinguishing feature of physician-administered drugs concerns their frequently being prescribed, purchased and dispensed by physicians, thereby becoming a source of their medical practice gross operating margin. Knowing this, managed care organizations that might otherwise expend considerable energies in seeking less costly sources of supplies for physician-administered drugs, such as via the buying power of specialty pharmacies, are less

[249] Ernst R. Berndt, "The U.S. Pharmaceutical Industry: Why Major Growth In Times of Cost Containment?", *Health Affairs*, 20(2), March/April 2001, pp. 100-114.
[250] George J. Stigler, "The Economics of Information", *Journal of Political Economy*, 69:3, June 1961, pp. 213-225.
[251] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, p. D-10.

likely to invest in obtaining such information. Even if they do invest in such information gathering activities, if health plans shift to a third party supplier of the physician-administered drugs, they thereby might risk losing scarce specialty physicians from their physician network who have profited from the "spread". I alluded to this in Subsection F of Section III. Here I simply restate that the propensity for managed healthcare organizations to examine and monitor closely drug expenditures is understandably less in the case of physician-administered drugs relative to that for self-administered drugs.

189. In the context of this litigation, an example of the at best uneven flow of information involving physician-administered drugs is provided in the deposition of Paula Pfankuch, Senior Manager, Professional Reimbursement Programs, Blue Cross – Blue Shield of Illinois. Ms. Pfankuch implemented a policy of 150% of AWP reimbursement for non-chemotherapy drugs, but a 90% of AWP reimbursement for chemotherapy drugs. Apparently this differential physician reimbursement policy was implemented after the plan's Chief Medical Officer, Dr. Alan Korn, an oncologist, provided verbal information to Ms. Pfankuch that the 90% reimbursement was adequate for chemotherapy. According to Ms. Pfankuch, "Dr. Korn was an oncologist. He had a better feel for what it may cost an oncologist to acquire drugs."[252]

190. A third distinguishing feature of physician-administered drugs concerns their ambiguity in terms of whether they are paid for out of the medical vs. the prescription drug benefit. With self-administered drugs, this is not an issue, for these prescription drug expenditures are closely monitored in real time by PBMs employing impersonal and efficient information technology software. By contrast, the relatively small number of physician-

[252] Deposition of Paula Pfankuch, dated September 14, 2004, pp. 38-42, as cited in *Plaintiffs Appendix of Summary Charts in Support of Class Certification*, December 17, 2004, Appendix 1(b), pp. 21-22.

administered claims is often handled by humans, and on a more individualized basis. For example, a specialty pharmacy reference source states:

> "Physician relationships – essential though they are – place obstacles to efficient claims processing and reimbursement of specialty pharmaceuticals. Unlike oral medications that use electronic claims adjudication, injectable drugs are often reimbursed through claims payment using human coding processes (J-codes, etc.). Even in systems where injectable drugs are adjudicated through the specialty distributor process, most physicians maintain their paper reimbursement processes. In this reimbursement process, the human adjudicator factor may result in substantial overpayment for certain injectable medications."[253]

An industry trade publication reporting on a 2004 forum in which major challenges facing the management of specialty drugs were discussed, noted the following strategy for data management:

> "Improved data management. With about 70% of specialty pharmacy still reimbursed as a medical benefit and many plans managing 10 to 15 different specialty pharmacy vendors, experts agreed that tracking patient data is nearly impossible. These issues make it difficult to tell payers where their money is going, said Lotvin. Medco Health is now attempting to integrate its medical specialty data with its pharmacy data by using a database to 'crosswalk' the J-code to the National Drug Code (NDC). Once Medco Health integrates that information on the PBM side, it can apply pricing disciplines and utilization management, and identify duplicate claims, said Russek.[254]

In a different industry publication, an executive at AdvancePCS reports that in his experience health plans become "flabbergasted at what they've been paying for years on drugs" on the medical side because of dramatic price markups.[255]

191. In summary, when medical benefit expenditure data are poorly monitored and "tracking patient data is nearly impossible", and when this is widely known, possibilities for

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[253] AIS [2003], *supra*, p. 73.

[254] "Specialty Benefit Management Is Next Step In Biotech Market Evolution, Experts Say", reprinted from the June 11, 2004 issue of Drug Cost Management Report, p. 3. Available online at http://www.aishealth.com/DrugCosts/specialty/DCMRSpecialtyBenefitBiotec.html, last accessed 12/29/04. Allan Lotvin, M.D., is President of Specialty Pharmacy Services at Medco Health Solutions, Inc. (p. 1). Steve Russek is Medco Health's Vice President, Product Development, Specialty Pharmacy (p. 2).

[255] "AdvancePCS Views Its Specialty Rx as Complementary to Caremark's Approach," reprinted from the January 2004 issue of *Specialty Pharmacy News*, p. 4. Available online at http://www.aishealth.com/DrugCosts/specialty/SPNAdvancePCSComplementCaremark.html, last accessed 12/29/2004.

mischief and abuse arise. That appears to be the case for physician-administered drugs adjudicated under the medical benefit.

192. A fourth and related distinguishing feature of physician-administered vs. self-administered drugs concerns how the utilization and pricing of distinct products are tracked. Stephen W. Schondelmeyer and Marian V. Wrobel have described the detailed 11-digit coding system for self-administered drugs:

> "Every firm that markets a prescription drug in the United States must register with the FDA to obtain a unique national drug code (NDC) number (11-digit) for each product marketed. The first part of the NDC, the labeler code (5-digits), uniquely identifies the firm marketing the drug product. The second segment, the product code (4-digits), identifies a specific strength, dosage form, and formulation for a given drug product. The third segment, the package code (2-digits), identifies package sizes and package types (e.g., bulk, unit dose, or unit of use). Both the product and package codes are assigned by the firm and not by the FDA.
>
> Manufacturers or marketers, who want to be assured that the Medicaid program will cover their drug products, must sign a national drug rebate agreement with the Secretary of the Department of Health and Human Services in order for states to receive federal funding for outpatient drugs dispensed to Medicaid patients."[256]

PBMs utilize these 11-digit NDC codes to monitor in real time the dispensing activities of network retail and mail order pharmacies, and immediately alert the dispenser if there are any suspected adverse interaction issues with other self-administered drugs being taken concomitantly, or with payment problems regarding adjudication of the claim. This 11-digit NDC coding system therefore facilitates the efficient electronic monitoring and processing of self-administered prescription drug purchases at the point of service.

193. In contrast, the Healthcare Common Procedure Coding System (HCPCS) established by CMS is based on a number of different 5-digit (one letter plus four numerical digits) codes, commonly known as J-codes and Q-codes. Providers use HCPCS J-codes to bill

[256] Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*," Introduction, Final Report, Contract #500-00-0049, Task Order 1, August 30, 2004, Cambridge, MA: Abt Associates Inc, pp. 9-10.

the Medicaid program for injectable prescription drugs, including cancer drugs.[257] Examples of the 5-digit J-codes are J1440 for Neupogen, J1950 for Lupron, and J9202 for Zoladex. Another 5-digit J-code is J2941, which covers a host of human growth factor products, having brand names Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Nutropin, NutropinAQ, Nutropin Depot, Salzen and Serostim.[258] An example of a 5-digit Q-code is Q4055, which is the new CMS HCPCS code for erythropoietin ("EPO") administered to patients with end stage renal disease.[259]

194. Unlike the 11-digit NDC codes for self-administered drugs, the 5-digit J-codes for physician-administered drugs are not unique for product size, packaging or dose, implying that a single billable J-code can be composed of numerous distinct NDC codes, thereby obfuscating not only which particular NDC product was actually administered, but how many units were utilized. This creates significant difficulties in tracking physician-administered drug utilization and unit prices. For example, an industry trade publication called Managed Care Week compared the NDC vs. J-codes, and noted implications for reliable monitoring of prices and utilization:

> "Retail pharmacy systems already have a lot of checks and balances that ensure, for example, that medications are priced correctly and are on the managed care plan's formulary, she says. By comparison, pricing of specialty pharmacy medications is much less controlled in the medical claims system. That makes it much more difficult for managed care companies to know how much they're spending and on which drugs.
>
> Part of the problem is the 'J-codes' established by CMS to identify certain drugs and other items. These codes aren't unique for product size, packaging or dose, so it's impossible to tell from the claim how much of the medication was administered. Secondly, there are many injectable products for which no J-code exists, so claims are submitted using a miscellaneous J-code instead…. Because of the lack of detail in J-

[257] Letter from Dennis G. Smith, Director for Center for Medicaid and State Operations addressed to State Medical Directors, dated March 14, 2003. Available online at http://www.cms.hhs.gov/states/letters/smd031403.pdf, last accessed 2/7/05.
[258] AIS [2003], *supra*, pp. 91-92, Figure 5-4, "Specialty Drugs Available Through McKesson for HMO Blue Texas Patients".
[259] "Clarification of Epoetin Alfa (EPO) Billing Procedures and Codes in ESRD", available online at http://www.cms.hhs.gov/medlearn/matters/mmarticles/2004/SE0406.pdf, last accessed 2/7/05.

codes, health plans could be at the mercy of the provider to get a fair price for a given drug."[260]

Moreover, since the J-codes are commonly used when providers bill Medicare or other commercial carriers, unlike the real time NDC-code based transactions monitoring by PBMs, with J-codes the monitoring is *ex post*. As one industry analyst put it, "With the J-code, most of the billing is retrospective, and you find out about issues 60 to 90 days too late, after the event occurs."[261]

195. Defendants' Expert Steven J. Young acknowledges difficulties that arise when J-codes encompass multiple NDC codes for branded single source physician-administered drugs, as well as from the fact that a single J-code typically covers all NDCs from various generic manufacturers selling a multisource physician-administered drug.[262] He also points out that relative to the highly automated processing of claims based on NDCs and their links to AWPs, "The claim processing for J-code claims, however, requires a relatively manual process to determine the quantity of the drug administered and then determine the appropriate reimbursement level for that drug."[263] One industry observer estimated that the cost of electronically processing a self-administered drug claim typically runs between 25 and 50 cents, versus about $45 for staff to handle a typical paper-based medical claim.[264]

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[260] "To Overhaul Specialty Pharmacy Practices, First Step In to Identify Current Policies", reprinted from the 4/17/03 issue of Managed Care Week, p. 2. The "she" to which the article refers is "Kim McDonough, Pharm.D., founder of North Kingstown, R.I.-based pharmacy consulting firm Advanced Pharmacy Concepts" (p. 1). Available online at http://www.aishealth.com/DrugCosts/MCWPharmoverhaul.html, last accessed 12/28/04.
[261] "AdvancePCS Views Its Specialty Rx as Complementary to Caremark's Approach", reprinted from the January 2004 issue of *Specialty Pharmacy News*, quoting Mike Ellis, senior vice president of specialty pharmacy for AdvancePCS, p. 3. Available online at http://www.aishealth.com/DrugCosts/specialty/SPNAdvancePCSComplementCaremark.html, last accessed 12/29/04.
[262] *Sur-Reply of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, January 20, 2005, pp. 22-26, Paragraphs 36-45..
[263] *Sur-Reply of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, January 20, 2005, p. 23, Paragraph 39.
[264] "Advance PCS Views Its Specialty Rx as Complementary to Caremark's Approach," reprinted from the January 2004 issue of *Specialty Pharmacy News*, attributing remarks to Mike Ellis, senior vice president of specialty

196. Plaintiff's Expert Dr. Raymond Hartman also acknowledges the lack of specificity in the J- and Q-coding detail. For example, in a footnote Dr. Hartman states:

> "A J-code is a special code developed by the Health Care Financing Administration (now CMS) for Medicare reimbursement purposes that is now frequently used by hospitals and physician offices to identify primarily injectable drugs administered to a patient. Typically there is only one J-code for a particular drug that may include multiple NDCs. A Q-code is essentially a temporary code assigned by CMS until a permanent J-code is assigned."[265]

In referencing Defendants' Expert Steven J. Young's use of several J-codes having multiple NDCs, Dr. Hartman notes that over the relevant time period, Procrit had a single Q-code but eleven NDCs being sold and reimbursed, and that the five-digit codes for Albuterol, Imitrex and Blenoxane each had four NDCs being sold.[266] This leads Dr. Hartman to attack the credibility and usefulness of analyses prepared by Defendants' Experts Steven J. Young and Dr. Eric M. Gaier: "I conclude that the analyses by these experts of physician-administered drugs for J-codes with multiple NDCs are of little or no evidentiary value."[267] Defendants' Expert Steven J. Young then points out that if Dr. Hartman is correct, this very critique undermines Dr. Hartman's ability to conduct reliably his analysis of physician-administered drugs without undertaking significant individual inquiry.[268]

197. This raises the issue of how easy and reliable it is to crosswalk from J-code to NDC-code claims. A March 14, 2003 letter from Dennis G. Smith, Director of the Center for Medicaid and State Operations, summarizes the process as follows:

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pharmacy for AdvancePCS, p. 4. Available online at http://www.aishealth.com/DrugCosts/specialty/SPNAdvancePCSComplementCaremark.html, last accessed 12/29/04.

[265] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, fn. 59, p. 37.

[266] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, fn. 60, p. 38.

[267] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, p. 38.

[268] *Sur-Reply of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, January 20, 2005, p. 4.

> "The process of crosswalking J-codes and other HCPCS-coded drugs to corresponding NDCs is very simple in cases where there is a one-to-one relationship between the J-coded drug and the NDC number. It can be more labor intensive where one J-code correlates to different NDC numbers…We are aware that private contractors have developed innovative systems that crosswalk J-codes to corresponding NDCs, including doing an in-pharmacy review of claims where necessary. These systems allow states to identify NDCs for the J-codes and bill manufacturers for rebates for these drugs."[269]

Just how labor intensive crosswalking will be, and how individualized the process will need to be in order to be reliable, particularly going back in time to the 1990s, is unclear to me at this point. This is an important issue that merits thoughtful and concise clarification by both Plaintiffs' and Defendants' experts.

198. What is clear, however, is that because physician-administered drugs have traditionally been reimbursed by J-code claims that often encompass a variety of distinct NDC entities, in many cases it has been difficult for healthcare organizations to monitor and observe the utilization and pricing trends underlying their expenditures on physician-administered drugs.

199. The issue of pricing transparency has been raised extensively by Plaintiffs in regard to PBMs and their management of purchases of self-administered drugs. I have dealt with that issue extensively in Section IV of this report. It is clear to me, however, that when it comes to physician-administered drugs, issues of pricing transparency become an order of magnitude larger. This creates opportunities for mischief and abuse that are very different from and much more obvious than in the case of self-administered drugs.

200. In conclusion, the continuing diverse ownership patterns of PBMs, the long series of investigations and continuing scrutiny of PBMs by various federal and state government agencies, the presence of audit privileges concerning "secret" PBM rebates as negotiable items in contracts, and the ubiquity of standardized and impersonal electronic transactions, together have

[269] Letter from Dennis G. Smith, Director, Center for Medicaid and State Operations, dated March 14, 2003. Available online at http://www.cms.hhs.gov/states/letters/smd031403.pdf, last accessed 2/7/05.

exerted a market discipline on the behavior of PBMs, generating a market-determined amount of transparency, and making competition among them "vigorous" in the market for self-administered drugs, as has been stated repeatedly by the FTC. By contrast, in the market environment for physician-administered drugs, a variety of forces – the relatively small dollar amounts they involve, the ambiguity of whether the claims stem from the medical or drug component of the health benefit, the troublesome relationships with providers who act as both buyers and sellers (and prescribers and dispensers) of physician-administered drugs, and the J-code claims system that has obfuscated the utilization and pricing of individual drug products and confounded close monitoring -- have together contributed instead to a system lacking checks and balances and inviting abuse. Some of that abuse has already been uncovered in this Court and elsewhere.

VI. INITIAL OBSERVATIONS ON THE METHODOLOGY PROPOSED BY DR. HARTMAN, AND ON ISSUES REGARDING CLASS CERTIFICATION

201. Numerous observers, as well as participants in this litigation, have commented on how complex and complicated are the relationships among agents interacting in the US pharmaceutical marketplace. While that may well be true, it is useful to place today's environment into historical perspective.

202. Recall that thirty years ago, patients actually spoke with their pharmacists, and if they had drug insurance coverage (which most did not), they carefully saved receipts from their cash/credit card prescription purchases, put them into a shoe box, and then at the end of a quarter or a year, collected the receipts, filled out forms by pencil, and sent receipts plus forms to their insurer for reimbursement. Information technology, screen monitors and modems were not to be found in this process.

203. Observers of pharmacy transactions at that time complained frequently about how widely prescription prices varied, not just among pharmacies, but even within pharmacies, depending on what pharmacist filled the prescription. For example, writing in the *Journal of the American Pharmaceutical Association* in 1973, Albert I. Wertheimer summarized his findings on intrapharmacy pricing variability for identical prescriptions dispensed in Buffalo, New York, as follows:

> "It is concluded that many pharmacies all too casually calculate the charges for their services. The charge for pharmaceutical services should not depend upon which pharmacist is on duty or upon the practitioner's mood, but rather upon sound professional and management principles. It is concluded that pharmacy managers fail to accurately convey their fee policies and techniques to their fellow pharmacists at their pharmacy and that far too little attention is paid to the effects of charge inconsistency.
>
> The concept of usual and customary fees is dealt a bitter blow in those pharmacies where there is but one usual and customary component to prescription pricing – randomness."[270]

Four years later, in an article entitled "The Mysteries of Prescription Pricing in Retail Pharmacies" published in the peer-reviewed journal *Medical Care*, the coauthors also report finding substantial interpharmacy price variability, as expected, but also intrapharmacy pricing heterogeneity. They also suggest a possible anti-competitive conspiracy:

> "What is surprising, however, is that the data show that within a two-week period, the price of the same quantity of the same dosage form of the same drug in the same pharmacy also varies by as much as 130 percent. The findings are consistent with the hypothesis of anti-competitive pricing which, by denying consistent price information to the consumer, makes rational purchasing behavior impossible." [271]

While today's health care markets are undoubtedly complex and perhaps even convoluted, it is worth remembering that issues involving the lack of transparency in the pricing of prescription pharmaceuticals have a considerable history in the US, as do the conspiracy theories that attempt

[270] Albert I. Wertheimer, "Pricing Pharmaceutical Service – Art, Science or Whim," *Journal of the American Pharmaceutical Association*, Vol. NS13, No. 1, January 1973, p. 12.
[271] S. E. Berki, J. W. Richards, and H. A. Weeks, "The Mysteries of Prescription Pricing in Retail Pharmacies", *Medical Care*, Vol. 15, No. 3, March 1977, p. 241.

to explain them. In this context, it is somewhat ironic that Stephen Schondelmeyer and Marian V. Wrobel have commented that due to the fact that the proportion of self-pay or cash prescriptions has fallen from about 56% in 1992 to about 15%, this has "greatly reduced the pharmacy's pricing flexibility."[272]

204. I have argued at length in this report that the management and distribution of prescription drugs differs substantially and materially in the self-administered vs. physician-administered market segments. While PBMs have become involved in one way or another in almost all transactions involving self-administered drugs, their role in managing physician-administered transactions is relatively minor, although increasingly they are aligning themselves with specialty pharmacies in the physician-administered market segment. To the best of my knowledge, PBMs did not play any major role in the egregious examples of fraudulent pricing and marketing involving sales of Lupron and Zoladex to physicians. Both Lupron and Zoladex are injectable medicines. Lupron is typically administered in a physician's office as a single intramuscular injection, frequently in the buttock, whereas Zoladex is administered subcutaneously in the upper abdominal wall using an aseptic technique under the supervision of a physician.[273] It is therefore somewhat confusing and misleading when, for example, Plaintiff's

[272] Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Introduction, Final Report, Contract #500-00-0049, Task Order 1, Cambridge, MA: Abt Associates Inc, August 30, 2004, p. 12.

[273] Various depot formulations of Lupron are pictured on p. 337 and described on pp. 3281-3292 in *Physicians' Desk Reference*, PDR 56 Edition 2002, Montvale NJ: Medical Economics Company; ranging in strength from 3.75 mg to 40 mg (fourth months formulation). The labeling for each of these depot administrations states "LUPRON DEPOT Must Be Administered Under The Supervision Of A Physician (p. 3283 for 3.75 mg depot, p. 3285 for 7.5 mg depot, p. 3287 for three month 11.25mg, p. 3289 for three month 22.25 mg, p. 3291 for four month 30 mg, and p. 3292 for the pediatric 7.5 mg, 11.25 mg and 15 mg formulations. Lupron is also supplied in a 2.8 ml multiple dose vial , with each 0.2 ml containing 1 mg of active ingredient (p. 3280). This formulation can be administered by a patient/parent or health care professional (p. 3281), and is pictured on p. 337. Zoladex injection is pictured on p. 306 of the same PDR 2002, and its 3.6 mg implant and three-month 10.8 mg implant formulations are described on pp. 702-708. Both dosage forms should be administered "into the upper abdominal wall using an aseptic technique under the supervision of a physician" (p. 705 for 3.6 mg implant, p. 708 for 10.8 mg implant (three-month))

Expert Dr. Raymond S. Hartman concludes that competition among PBMs is insufficient, citing as support the physician-administered Lupron scandal:

> "The analyses put forward by Defendants' experts, particularly Dr. Gaier, are flawed and insufficient to demonstrate that existing PBM competition, specifically, and provider competition, generally, were sufficient to eliminate the AWP scheme. If such competition exists, it should have been sufficient to dissipate and eliminate the significant payor injury and economic damages found and pled guilty to in the Lupron matter. It was not."[274]

This is a massive case, and in dealing with it the distinction between self-administered and physician-administered drugs is necessary and useful.

A. Self-Administered Drugs

205. Both sides in this matter agree that in the context of self-administered drugs, PBMs play a central role; I have documented those views earlier in this report. Plaintiffs allege that competition among PBMs is not effective.[275] The Federal Trade Commission appears to disagree. While competition among PBMs may not conform to the undergraduate microeconomics textbook example of a perfectly competitive market (in which all buyers are either fully or at least equally informed, and everyone is a price taker), federal regulatory authorities have concluded that PBM competition is "vigorous".

206. Specifically, over the years the PBM industry has been closely monitored by the FTC (in both the Clinton and subsequent Bush administrations), and in some cases when it concluded competition might be harmed, it used its regulatory powers to intervene (e.g., to require firewalls between drug manufacturers and the PBMs they owned). As late as last year, in the context of investigating possible anticompetitive effects of horizontal consolidation among

[274] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, pp. 19-20.
[275] See, for example, *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, pp. 19-20, 72-82.

two of the largest PBMs -- the Caremark/ AdvancePCS acquisition -- the FTC allowed the transaction to go forward, stating:

> "We concluded that these large employers are not likely to encounter anticompetitive effects from the acquisition in light of the competition that will exist following this transaction. Competition from the remaining independent, full-service PBMs with national scope – Medco, Express Scripts, and the merged Caremark/Advance PCS {Footnote 3 Not Reproduced} – and significant additional competition from several health plans and several retail pharmacy chains offering PBM services should suffice to prevent this acquisition from giving rise to a potentially anticompetitive price increase…"[276]

> "At most, the acquisition is likely to increase the bargaining power of the merged PBM and to increase its shares (and correspondingly reduce the pharmacies' shares) of the gains flowing from contracts between the PBM and the pharmacies. It is likely that some of the PBM's increased shares would be passed through to PBM clients {Footnote 6 Here Reproduced Next}. We anticipate that competition among PBMs will remain vigorous in the wake of the Caremark/AdvancePCS acquisition, and that this competition is likely to cause PBMs to pass on at least some of their cost savings to their customers in order to gain or retain their business."[277]

In the context of self-administered drugs, therefore, Plaintiffs' arguments and conclusions appear to be at variance with those of the FTC, and my own analysis discussed earlier in this report. If competition among PBMs is vigorous, even if the self-administered AWPIDs were artificially inflated, injury and damages to third party payors do not follow, particularly on a class-wide basis. Since lack of competition among PBMs is crucial to Plaintiff's theory, this would appear to undermine their allegations, and certainly their assumption of class-wide injury and damages. Plaintiffs have not, in my judgment, addressed this issue effectively.

207. In support of their claim that competition among PBMs is not sufficient, Plaintiffs point to the facts that even as the "spread" between AWP and ASP facing retail and mail order

[276] Statement of the Federal Trade Commission, *In the Matter of Caremark Rx, Inc./Advance PCS*, File No. 031 0239, p. 2. Available online at www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf, last accessed 1/16/05.
[277] Statement of the Federal Trade Commission, *In the Matter of Caremark Rx, Inc./Advance PCS*, File No. 031 0239, p. 3. Available online at www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf, last accessed 1/16/05.

pharmacies for generic drugs has increased over time, the average reimbursement rates for generic self-administered drugs paid by third party payors to retailers have not fallen commensurately, implying that pharmacies have benefited and that PBMs have not been able provide a competitive market discipline on these generic drug transactions.[278] Plaintiffs' empirical argument that retail (and PBM mail order) "spreads" for generic self-administered drugs have grown more rapidly than have reductions in reimbursements paid by third party payors to retailers is credible. But even if true, this does not necessarily imply a lack of effective competition among PBMs.

208. As I pointed out earlier in this report, generic drug costs are typically only 10-20% of third party payor total prescription drug costs, and third party payors are understandably gratified whenever they achieve a generic for brand substitution switch. Once having achieved a cost saving from the substantial price difference between a brand and its bioequivalent generic, the third party payor (and or its PBM) understands that the additional, incremental savings it might obtain from negotiating lower generic prices with retailers are likely to be relatively small. However, even when relatively small, those incremental cost savings are present, and perhaps it is that possibility that the FTC referred to in the second paragraph of the above FTC quote when it envisaged possible increased buying power for PBMs resulting from the Caremark/ AdvancePCS acquisition. The FTC footnote quoted above also suggests the FTC expected part of the lower prices obtained by PBMs in their dealings with retailers would be passed on to third party payors and their beneficiaries.

209. In summary, the Plaintiffs' theory in the context of self-administered drugs requires that competition among PBMs be insufficient to prevent injury and damages to third

[278] See, for example, *Declaration of Raymond S. Hartman In Support of Plaintiffs' Motion for Class Certification,* September 3, 2004, p. 13.

party payors. In my judgment Plaintiffs have not put forward a convincing argument supporting the notion that competition among PBMs is inadequate. Plaintiffs' contention is also at variance with conclusions reached by the FTC.[279]

210. There is one other matter that merits attention in this context. Even if Plaintiffs argument concerning lack of competition among PBMs were true, to the extent they owned and operated their own PBMs (and recall that the ownership structure of the PBMs has been and continues to be very diverse), third party payors would seem to me to have benefited from the allegedly fraudulent AWP scheme, and thus they would appear to face conflicts as members of the proposed class. I will not comment on this further.

211. Issues of typicality, commonality and variability are frequently at the crux of deliberations involving class certification. Before addressing some of those issues, however, I first summarize my understanding of the methodology that Plaintiff's Expert Dr. Raymond Hartman proposes to employ in assessing class-wide liability and damages.

212. In assessing whether the proposed end-payer classes were damaged, Plaintiffs' Expert Dr. Hartman proposes first to compute the spreads between AWP and ASP "for drugs unaffected by the scheme and fraud", and then use these as "yardsticks" in comparison with spreads observed "for the drugs subject to this litigation". In cases where he determines the latter spreads are larger than the former, Dr. Hartman proposes to employ his yardsticks along with mathematical and algebraic formulae "to determine the spread that would have been used

[279] This is not to say that PBMs are currently exempt from litigation and government investigations. See, for example, "The United States Settles Its Anti-Fraud Claims for Injunctive Relief and 20 State Attorneys General Settle Unfair Trade Practices Claims Against Medco Health Solutions: Medco to Provide Price Information to Doctors and Patients and Pay $29 Million Plus To States in Damages, Fees, and Restitution – Federal Damages Case Continues", U. S. Department of Justice press release, April 26, 2004, available online at www.usdoj.gov/usao/pae/News/Pr/2004/apr/medcoinjunctivereliefrelease.pdf, last accessed 12/31/2004.

for the affected drugs but-for the wrongful scheme", thereby determining "the overall class-wide injury and damage for each drug".[280]

213. A critical component of this methodology is the comparison between the spreads achieved by AWPID "artificially inflated" drugs with those achieved by drugs "not subject to this Litigation".[281] The choice of comparator drugs, and time periods, is important and requires considerable care, particularly in isolating the impact of the allegedly fraudulent pricing scheme. I note that the results obtained from the comparator analyses by Dr. Hartman will then become a critical part of his construction of "but for" prices for the AWPID drugs at issue.

214. There are many factors that can affect a manufacturer's decision on how to set AWP, ASP, and therefore their difference. For self-administered single source, brand name drugs (such as those sold by competing oligopolists/monopolists, as I discussed in Section IV above), a number of factors affect not only the launch price (both AWP and ASP) of a newly FDA-approved drug, but will also affect the trajectory of pricing (both AWP and ASP) as the competitive landscape changes. Among the medical and economic factors that the literature suggests affect the price schedule of single source, brand name self-administered drugs during the product's life cycle are the following:[282]

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[280] *Plaintiffs' Memorandum In Opposition to Defendants' Motion to Strike the Hartman Declaration*, December 17, 2004, p. 3.

[281] The words "drugs not subject to this Litigation" are taken from *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, p. 9. Drugs not subject to this litigation could apparently include non-AWPID drugs from Defendant manufacturers, or drugs from non-Defendant manufacturers. In the same document, Dr. Hartman states on p. 9, "I have reviewed data for Defendant Drug Manufacturers' drugs not subject to this Litigation, and I plan to review similar data for non-defendant drug manufacturers should discovery allow."

[282] The literature is substantial. Some of the more well-known studies (that contain reference to many other studies) include: Richard E. Caves, Michael D. Whinston and Mark A. Hurwitz, "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry," *Brookings Papers: Microeconomics 1991*, Washington DC: The Brookings Institution, 1991, pp. 1-48; Z. John Lu and William S. Comanor, "Strategic Pricing of New Pharmaceuticals", *Review of Economics and Statistics*, Vol. 80, No. 1, February 1998, pp. 108-118; Alan T. Sorensen, "Equilibrium Price Dispersion in Retail Markets for Prescription Drugs", *Journal of Political Economy*, 108(4), August 2000, pp. 833-850; Sara Ellison, "Recent Patterns in Antibiotics Pricing", Cambridge, MA: MIT Dept. of Economics, September 1997; Mark Duggan, "Do new prescription drugs pay for themselves? The case of second-generation

- whether the product treats an acute vs. a chronic condition (e.g., frequency of purchase);
- therapeutic class (e.g., psychotropic vs. statin);
- class of trade purchaser (e.g., chain pharmacy, mass merchant pharmacy, food and drug pharmacy, independent pharmacy, mail order pharmacy, health plan pharmacy, clinic and physicians' office, long term care pharmacy, hospital, government facilities and other);
- number of single-source brand name competitors in the same therapeutic class;
- whether any brands in the same therapeutic class are multisource, i.e. have generic competitors;
- time before expected patent expiration and initial generic entry;
- side effect, efficacy and convenience profiles relative to competitors in the class;
- substitutability with and cost of non-pharmacological treatments (e.g., psychotherapy vs. antidepressant therapy);
- substitutability with and cost of non-Rx versions (e.g., over-the-counter competition); and
- initial FDA priority designation (historically, FDA ratings of A, B or C, and more recently, standard vs. priority).

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antipsychotics", *Journal of Health Economics*, 24(1), January 2005, pp. 1-31; Ernst R. Berndt, Robert S. Pindyck and Pierre Azoulay, "Consumption Externalities and Diffusion in Pharmaceutical Markets: Antiulcer Drugs", *Journal of Industrial Economics*, 51(2), June 2003, pp. 243-270; Ernst R. Berndt, Ashoke Bhattacharjya, David Mishol, Almudena Arcelus and Thomas Lasky, "An Analysis of the Diffusion of New Antidepressants: Variety, Quality, and Marketing Efforts", *The Journal of Mental Health Policy and Economics*, Vol. 5, No. 1, March 2002, pp. 3-17; Ernst R. Berndt, "Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price", Journal of Economic Perspectives, 16(4), Fall 2002, pp. 45-66; Ernst R. Berndt, Iain M. Cockburn and Zvi Griliches, "Pharmaceutical Innovation and Market Dynamics: Tracking Effects on Price Indexes for Antidepressant Drugs," *Brookings Papers on Economic Activity: Microeconomics*, 1996:2, pp. 133-188; and Ernst R. Berndt, Linda T. Bui, David H. Reiley and Glen L. Urban, "Information, Marketing and Pricing in the U.S. Anti-Ulcer Drug Market", *American Economic Review,* 85(2), May 1995, pp. 100-105.

215. With a host of factors known to affect the pricing path of a brand name, single source self-administered drug through its life cycle from launch to facing generic competition, the challenge facing Plaintiff's Expert is the following: How can it be determined that at any given point in time, it is one or more of the above factors that affected and were largely responsible for the price decisions made by defendant manufacturers during the product's life cycle, rather than Defendants' alleged AWP scheme to collect inflated prescription drug payments? Simply examining and recording larger differences in percent "spreads" between each AWPID drug and "drugs not subject to this Litigation" will not be sufficient to establish reliably that any differential "spread" is attributable solely, partly or not at all to the alleged AWP scheme to collect inflated prescription drug payments. Other factors could instead contribute to the differential "spread", to varying extents across drugs and time.

216. For a given AWPID drug, the choice of comparator "drugs not subject to this Litigation" will be critical. One possibility would be to choose as comparators one or more single source, branded self-administered drugs otherwise very similar to the AWPID drug but for its manufacturer's alleged pricing behavior. That is likely to raise a variety of medical and clinical issues requiring expertise from medical experts, and in any case, necessitates individualized drug-specific rather than class-wide treatment.

217. An alternative procedure that could attempt in a more sophisticated statistical manner to control for factors other than the manufacturer's alleged illegal behavior would involve use of multiple regression analysis, and what has come to be known as hedonic price analysis.[283] Dr. Hartman refers to this somewhat briefly in his deposition, when asked about the

[283] A discussion of the rationale underlying hedonic price analyses, and its history, is found in Ernst R. Berndt, "The Measurement of Quality Change: Constructing an Hedonic Price Index for Computers Using Multiple Regression Methods", ch. 4 in Ernst R. Berndt, *The Practice of Econometrics*: Classic and Contemporary, Reading MA: Addison-Wesley, Inc., 1991, pp. 102-149.

Kennett piano mover price fixing case in Massachusetts in which he had been retained as an expert for class certification purposes.[284] In that deposition he refers to an article he jointly authored in the *Journal of Law, Economics, and Organization* that focused on the use of hedonic price analysis for certification and damage calculations in class action complaints.[285]

218. In his Rebuttal Declaration Dr. Hartman provides several examples of multiple regression equations he has estimated that could be interpreted as hedonic price regressions. Each of these regressions relates the actual acquisition prices of a drug (and whether these include all rebates is unclear) to its AWP. This is done for five single source branded self-administered drugs (although several such as Paxil, Coumadin and Claritin have generic competition by the end of the class time period). In each of these regressions, no comparisons are made with "drugs not subject to this Litigation".[286] It is therefore unclear to me at this time precisely how Dr. Hartman plans to proceed with hedonic price analysis, and at how aggregated a level that analysis will take place. A literature has also recently developed that critiques the usefulness of intertemporal hedonic regressions when the products are undergoing substantial quality improvement, and markets are rapidly changing. Clearly the markets for both self-administered and physician-administered drugs have undergone very substantial changes over

[284] Deposition of Raymond S. Hartman, Ph.D., Boston, Massachusetts, October 7, 2004, Vol. 1, pp. 293-300.
[285] I believe the referenced article is Raymond S. Hartman and Michael J. Doane, "The Use of Hedonic Analysis for Certification and Damage Calculations in Class Action Complaints", *Journal of Law, Economics and Organization*, 3(2), Fall 1987, pp. 351-372. Two other articles by Dr. Hartman dealing with hedonic price analysis are: Raymond S. Hartman, "Product Quality and Market Efficiency: The Effect of Product Recalls on Resale Prices and Firm Valuation", *Review of Economics and Statistics*, 69(2), May 1987, pp. 367-371; and Raymond S. Hartman, "The Use of Statistical Methods in Disparate Impact Cases: The Northern Mariana Islands Case," *Litigation Economics Digest*, Publication of the National Association of Forensic Economics, Vol. 3, 1998, pp. 1-25.
[286] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, Attachment E, and pp. 47-49.

time. This can make assumptions of intertemporal stability in hedonic price analysis problematic.[287]

219. Professor Stephen Schondelmeyer and Marian Wrobel have pointed out that there are substantial acquisition cost differentials by class of trade (naming ten of them)[288]. This suggests that class of trade distinctions would need to be taken into account when examining the differential spreads between "artificially inflated" drugs and "drugs not subject to this Litigation", by hedonic pricing analyses or other means. If the overall (rather than class of trade specific) spreads on the two sets of drugs are to be compared, to the extent class of trade acquisition differentials exist, the heterogeneity in distribution of each drug's sales by class of trade will also need to be taken into account.

220. Another issue in choosing comparator drugs involves the time period. Evidence from a survey of a substantial number of employers' health plans suggests that while in any given year there was non-trivial variation in the average discount off AWP obtained by health plans in their negotiated contracts with retailers and mail order services, over time this average discount has increased substantially. For brands, the annual 1995 through 2000 discount off AWP was 11.8%, 12.1%, 12.6%, 13.2%, 13.1% and 13.5%, respectively, while for mail order services the respective annual average discount off AWP was 15.0%, 14.6%, 16.6%, 17.1%, 17.4% and 18.5%.[289] Although I do not provide references here, I believe both sides acknowledge this general time trend in discount off AWP between 1995 and 2000, and I expect they would acknowledge that this general trend has persisted if not accelerated since 2000. I

[287] See, for example, Ariel Pakes, "A Reconsideration of Hedonic Price Indexes with an Application to PCs," *American Economic Review*, 93(5), December 2003, pp. 1578-1596.
[288] Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices,* Cambridge, MA: Abt Associates Inc., August 30, 2004, pp. 9-16.
[289] *The Takeda and Lilly Prescription Drug Benefit Cost and Plan Design Survey Report, 2001 Edition*, Tempe AZ: The Pharmacy Benefit Management Institute, Inc., Tables 9 and 10, p. 24. The tables also show that dispensing fees have typically been less for mail services than retail, and that the former have been falling more rapidly over time.

have cited evidence from the various OIG studies and the CBO earlier in this report; some of those studies are summarized in Attachment B.

221. Before discussing the issues in the choice of time frame when comparing spreads of drugs with "artificially inflated" prices to those "not subject to this Litigation", I briefly document below the time trend in the distribution of discounts off-AWP for self-administered drugs. As is seen in Tables 2 and 3 below, for brands the distribution of discounts off AWP has drifted upward over time, with slightly more homogeneity in 2000 than in the earlier 1995-6 years, although this change is not substantial. For mail order drugs, the entire distribution of discounts off AWP is not only larger ("Mail service discounts vary more than retail, as an individual employer's ability to get deep discounts depends on the demographics and utilization patterns of its patient population.")[290], but it appears also to have shifted over time, with a greater portion getting larger discounts.

Table 2

Percentage of Employers According to Retail Brand AWP Discount

Percentage of Respondents						
% off AWP	**2000**	**1999**	**1998**	**1997**	**1996**	**1995**
>15%	6%	6%	7%	3%	3%	0%
15%	20%	15%	15%	12%	10%	10%
14%	15%	10%	10%	6%	4%	4%
13%	40%	40%	36%	37%	33%	23%
12%	12%	20%	24%	26%	25%	26%
<12%	6%	8%	9%	17%	25%	37%

Source: *The Takeda and Lilly Prescription Drug Benefit Cost and Plan Design Survey Report*, *2001 Edition*; Tempe, Arizona: The Pharmacy Benefit Management Institute, Inc., Table 11, p. 24.

[290] *The Takeda and Lilly Prescription Drug Benefit Cost and Plan Design Survey Report, 2001 Edition*, Tempe, AZ: The Pharmacy Benefit Management Institute, Inc., Tables 11 and 12, p. 24.

Table 3

Percentage of Employers According to Mail Service Brand AWP Discount

	Percentage of Respondents				
% off AWP	**2000**	**1999**	**1998**	**1997**	**1996**
>20%	19%	6%	5%	4%	5%
20%	19%	17%	9%	9%	5%
19%	19%	10%	7%	6%	4%
18%	15%	20%	21%	15%	11%
17%	14%	15%	19%	18%	11%
16%	9%	14%	12%	17%	16%
15%	7%	8%	13%	14%	17%
<15%	4%	10%	14%	18%	31%

Source: *The Takeda and Lilly Prescription Drug Benefit Cost and Plan Design Survey Report*, *2001 Edition*; Tempe, Arizona: The Pharmacy Benefit Management Institute, Inc., Table 12, p. 24.

222. Dr. Hartman appears to suggest that in choosing comparator drugs and time periods, he may make only minimal use of the more recent data (since 1997), for two reasons. First, he argues that the market still has not digested recent information concerning the "artificially inflated" prices of AWPIDs:

> "Given the slowness with which the information in these studies is assimilated by this industry, the findings of the 1997-2002 reports began to affect the understanding and expectations about drug pricing only in the last few years. The relationships between AWP and AAC found in these studies are too recent to have informed pricing expectations for most of the Class Period."[291]

While there may be merit to this argument in the context of physician-administered drugs where for reasons I discussed in Section V information flows have been impeded and obfuscated, this is unlikely to be the case in the context of competing PBMs managing purchases of self-administered drugs, where competition has been vigorous.

[291] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, Attachment D, p. 8.

223. A second argument advanced by Dr. Hartman regarding why he may focus primarily on pre-1997 data is that the post-1997 marketplace and its data have been "contaminated to an unknown extent" by the allegedly fraudulent pricing scheme:

> "Given the allegations in this matter, the more recent (and larger) spreads reflect the AWP scheme to an unknown extent and are contaminated to an unknown degree for use as yardsticks for non-fraudulent pricing behavior".[292]

If the number and sales proportion of the allegedly fraudulently priced AWPID drugs in this litigation constituted a substantial portion of the total US market, such contamination might be possible. At her tutorial before Judge Saris on December 6, 2004, however, Professor Meredith Rosenthal noted that although there are about 65,000 drugs on the market, "the use of AWP as a pricing mechanism for the vast majority of these drugs is not at issue in the AMCC or in this motion". A footnote then elaborated as follows:

> "The fact that for 99% of prescriptions AWP works and is not being challenged highlights why AWP is an accepted pricing benchmark and further highlights why there was no widespread knowledge of the abuse alleged in the AMCC."[293]

It is not clear to me how Plaintiffs' argument that AWP "works" for 99% of prescriptions squares with Dr. Hartman's concern that post-1997 transactions of "drugs not subject to this Litigation" may have become contaminated by the allegedly fraudulent pricing scheme. In any case, as I understand it, while at this stage of the class certification process one assumes for the moment that the Plaintiffs' claims are true, it is not general practice at this stage to make even further assumptions, not alleged in the AMCC, about spillovers from the 1% of drugs at issue.

224. There is one final analytical point I wish to make concerning Dr. Hartman's proposed methodology. In what follows I will employ a minimum amount of algebra, using the

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[292] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, Attachment D, p. 8.

[293] *Written Tutorial of Meredith Rosenthal, Ph.D.*, presented to Judge Patti B. Saris, December 6, 2004, pp. 2-3 and fn. 2, p. 3. Also see transcript of Day One – Tutorial – Evidentiary Hearing (Meredith Rosenthal testifying), pp. 47-48.

symbol "Δ" to denote "difference in", so that, for example, "Δ AWP" means "difference in AWP". One definition of the spread for branded drug i at time t is: Spread(i,t) = AWP(i,t) – ASP(i,t). Similarly, for branded drug j at time t, the spread is: Spread(j,t) = AWP(j,t) – ASP(j,t). Suppose that between time periods t and t+1, the AWP on drug i increases, while ASP remains unchanged. Since revenues for a PBM under a typical contract with a third party payor increase formulaically with increases in AWP, other things equal, the PBM benefits from the Δ [AWP(i,t+1) – AWP(i,t)], and according to Plaintiffs' theory, the PBM is incented as a result to "move market share" of this drug i, at the expense of the third party payors. Note also that in this case, the only reason the total spread has increased is because of the increase in AWP, not any decrease in ASP.

225. Now consider the case when for drug j, the AWP between periods t and t+1 does not change, but the ASP falls, thereby increasing the "spread" for drug j between time periods t and t+1. Notice that this has no revenue impact and therefore no effect on the incentives facing the PBM to move market share for drug j, because any change in revenues per prescription depends on a change in AWP, and in this instance there has been no change in AWP, even though there has been an increase in the spread. [294]

226. As I understand it, as part of his establishing class-wide injury and damages, Dr. Hartman proposes to compare spreads for various drugs over various time periods, without accounting for whether (or what proportion of) the differential spreads are due to changes in AWP vs. those due to changes in ASP. For the PBM, only those differential spreads attributable

[294] I note in passing that Dr. Hartman believes that PBM rebates (which would affect their incentives) are not formulaically related to AWP. In his original Declaration, Dr. Hartman states: "The rebates paid to PBMs by the drug manufacturers were not formulaically related to AWP; they were additional financial incentives offered to PBMs to move market share." *Declaration of Raymond S. Hartman In Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, fn. 28, p. 12. At his deposition on October 7, 2004, an errata sheet indicated that instead of "…drug manufacturers were not formulaically…" should be changed to "…drug manufacturers generally were not formulaically…". See Exhibit 003 of the Deposition of Raymond S. Hartman, Vol. 1, October 7, 2004.

to changes or differences in AWP affect its incentives. Dr. Hartman has not addressed the issue of how he proposes to decompose differential spreads between the AWPID drugs being litigated here and those of "drugs not subject to this Litigation" into the set of transactions in which AWP was not changed while ASP was decreased (such transactions would appear to be excluded from the class, since PBMs' incentives are unaffected in such situations) from those differential spread transactions attributable at least in part to increases in AWP. I note that decomposing the source of the differential spread is unnecessary in the context of purchases of generic drugs by retailers, or of both brand and generic mail order operations (including those owned and operated by PBMs), for in those cases the incentive to prescribe/dispense a particular drug increases with the size of the spread, regardless of its source. Finally, in the context of PBMs, decomposition of the source of any differences in spread could depend on the periodicity of the data; to date, most of these calculations have been done on a quarterly rather than annual basis.

227. In terms of data issues, I have not of course delved into the data sets employed by the various experts in this litigation. It goes without further elaboration that the sales data will need to exclude hospital sales, and that all rebates given by manufacturers to PBMs, providers and third party payors, need to be taken into account when calculating the ASP, and spreads based on the ASP. Moreover, since rebates are typically computed ex post, their temporal allocation needs care.

B. Physician-Administered Drugs

228. In Section V of this report I noted that expenditures on physician-administered drugs were likely only at most 11% of total prescription drug expenditures in 2002, and that this share was even smaller in earlier years. In part because of this relative importance, and aided enormously by accounting ambiguities concerning whether physician-administered drugs were

covered by the medical or drug benefit, as well as a J-code classification system that obfuscated true transactions prices and utilization, the quality of general information concerning actual prices for physician-administered services is likely to have been very poor. The information that did exist was not necessarily useful because of substantial likely heterogeneity in how third party payors tracked and contracted with providers, thereby making questionable any generalizability of the available information. Specialty pharmacies, like PBMs, appear to have a relatively diverse ownership (which I will not document here), but because of other informational flow impediments, and the relatively small importance of physician-administered drug expenditures, these benefits from diverse ownership have been more than offset by information flow problems involving physician-administered drugs.

229. The "high touch, high cost" characteristic of the physician-administered drugs also implies that the statistical variance from any sample of information could be very high, further jeopardizing the reliability of any single information source. When so little is known, it is not clear whether certain features are in fact "typical". This will be a major challenge in considering the physician-administered portion of the class certification motion. Lack of appropriate information regarding injectables and other physician-administered drugs has also hindered effective public policy making.[295]

230. While this lack of information is gradually changing, and some payors such as TennCare have announced significant efforts in setting up systems to track specialty pharmacy utilization and prices more closely[296], it will be a challenge in this litigation to track down

[295] J. D. Kleinke, "Re-Naming and Re-Gaming: Medicare's Doomed Attempt to Reform Reimbursement for Injectable Drugs," *Health Affairs Web Exclusive*, 8 December 2004, 8 pp. Available online at http://content.healthaffairs.org/cgi/content/full/hltaff.w4.561/DC1, last accessed 1/12/05.

[296] "TennCare Plans to Implement Maximum Allowable Cost for Specialty Rx Early in '04", reprinted from the January 2004 issue of Specialty Pharmacy News, 4 pp. Available online at http://www.aishealth.com/DrugCosts/specialty/spntenncare.html, last accessed 12/29/04. Also see related article regarding the Tennessee Blue Cross Blue Shield plan data improvement initiatives for specialty pharmaceuticals:

reliable information going back in time, either on a class-wide or on an individualized basis. An additional complication occurs because in those cases in which physician services and the prescribing/dispensing of physician-administered drugs are bundled into overall specialty physician fee schedules, such fee schedules will likely have geographical variations, as well as urban-rural differences, reflecting the underlying heterogeneity in real estate costs, wages for physician assistants and office staff, and the shortage/surplus supply situation among various specialties of physicians.[297]

231. Since the amount of expenditures involved in physician-administered drugs is relatively small, and its growth to more substantial proportion is only quite recent, it is not surprising that relatively little useful information and analysis has appeared in the public policy and academic literatures concerning pricing trends and patterns. For example, while it is true that there is a substantial literature documenting the pricing and time path of entry for generic drugs (witness the very long list of references provided by Dr. Hartman in footnote 62 of his Rebuttal Declaration)[298], to the best of my knowledge, none of those cited papers deals with generic entry of injectables or other physician-administered drugs, and instead this literature focuses almost entirely on self-administered generic drugs.

232. In my own research and consulting, I have discussed generic entry patterns in the injectable and physician-administered drug sectors, but I cannot point to any relevant public domain literature. Without identifying specific companies and products, all I can say is that it is my perception that for injectables/physician-administered drugs, generic entry has typically not

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"Tenn. Blues Choose Three Specialty Rx Vendors, Create Product List", reprinted from the January 2004 issue of Specialty Pharmacy News, 5 pp. Available online at http://www.aishealth.com/DrugCosts/specialty/spnTennBlues.html, last accessed 12/29/04.

[297] This regional variability is discussed by Plaintiff's Expert Dr. Stephen W. Schondelmeyer, *Declaration of Stephen W. Schondelmeyer In Support of Plaintiff's Motion for Class Certification*, September 2, 2004, pp. 39-40.

[298] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, fn. 62, pp. 39-40.

been as rapid and as extensive as it has with self-administered drugs. Moreover, for those injectable/physician-administered drugs not having an oral formulation as well (i.e., tablet or capsule versions), generic prices tend to fall more slowly and not as sharply as do generic self-administered drugs. Finally, in cases where there is both an oral and an injectable/physician-administered formulation of the identical active ingredient, following loss of patent protection, generic entry and pricing tend to be quite similar for self-administered and injectable/physician-administered drugs. These are the only generalizations I can comfortably make in terms of price and entry patterns for self-administered vs. physician-administered generic drugs, and even for these, for confidentiality reasons I am unable to provide explicit examples and references.

233. As I have indicated earlier in this report, it will be critical to be able to crosswalk easily between J-codes and NDC codes. At this point in time I cannot comment on how labor-intensive such a process will be, and the implications for class certification.

C. Final Comments

234. I have intentionally entitled this section of my report "Initial Observations on the Methodology Proposed by Dr. Hartman, and on Issues Regarding Class Certification". The issues surrounding class certification are indeed complex, and I will continue to think and deliberate on them. I am available to discuss these matters further with the Court, should the Court deem that useful and appropriate.

Attachment A

CURRICULUM VITAE

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15 August 2004

PERSONAL DATA

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Place and Date of Birth	**Citizenship**	**E-mail Address**
Crespo, Entre Rios, Argentina 13 April 1946	U.S. Citizen	eberndt@mit.edu berndt@rcn.com

Education and Degrees:	B.A. (Honors) - 1968 Department of Economics Valparaiso University Valparaiso, Indiana 46383 M.S. (1971) and Ph. D. (1972) Department of Economics The University of Wisconsin Madison. Wisconsin 53706 Major Field - Public Finance Minor Fields - Demography, Econometrics D. Phil., Honorary (1991) Uppsala University Uppsala, Sweden
Ph.D. Thesis Title:	"The Economic Theory of Separability, Substitution and Aggregation with an Application to U.S. Manufacturing, 1929-1968"
Thesis Committee:	Laurits R. Christiansen, Chair Arthur S. Goldberger Charles E. Metcalf
Academic Awards:	Christ College Scholar, Valparaiso University (1965-1968) National Science Foundation Trainee (1969-1970) National Science Foundation Fellow (1970-1971 and 1971-1972) Most Cited Economist Under Age 40 in 1985 Journal of Economic Perspectives Vol. 3, No.4, Fall 1989, p. 143, and The Journal of Economic Education Vol. 20, No.4 Fall 1989, p. 413.

Academic Awards (continued):	Elected Fellow, The Econometric Society, 1994
	Distinguished Alumnus Award, Valparaiso University, March 31, 1996
	Excellence Award in Mental Health Policy and Economics Research, International Center of Mental Health Policy and Economics, Venice, Italy, March 2003 for article published in the March 2002 issue of The Journal of Mental Health Policy and Economics (see item #123 in publications listed below)
	Listed in Who's Who in America
Current Positions:	Professor of Applied Economics, MIT July 1, 1980 - present
	Awarded Louis B. Seley Chaired Professorship, February 1997
	Director, National Bureau of Economic Research, Program on Productivity and Technological Change, 2000 – present
	Adjunct Professor of Applied Economics, Harvard Medical School, Division of Health Care Policy and Research, 2001 - present
Previous Positions Held:	Research Economist Office of Emergency Preparedness Executive Office of the President U.S. Government Washington, D.C. September 1971 - December 1972
	Assistant Professor Department of Economics University of British Columbia January 1973 - June 1976

Associate Professor
Department of Economics
University of British Columbia
June 1976 - June 1980

Previous Positions Held (Continued):

Visiting Scholar
Department of Economics
Massachusetts Institute of Technology
July 1977 - June 1978

Visiting Scholar
Department of Economics
Stanford University
January - August 1985

Visiting Scholar
Harvard Business School
July 1990 - June 1991

Area Head, Economics, Finance and Accounting, MIT Sloan School,
July 1992 through June 1995

Visiting Professor of Applied Economics
Harvard Medical School, Division of Health Care Policy and Research
July 1996- June 1997

Other Professional Activities:

Elected Member and Member, Executive Committee
Conference on Income and Wealth
National Bureau of Economic Research
1978 - present

Panel Resource Group Member
U.S. National Academy of Sciences
National Research Council
Committee on Nuclear and Alternative Energy Systems (CONAES)
March 1976 - May 1978

Associate Editor of the Book Review Section, Journal of The American Statistical Association

1977 - 1981

Editorial Advisory Board
Resources and Energy
1979 - present

Member, Board of Editors
Energy Journal
1979 - 1988

Other Professional Activities (Continued):

Associate Editor
Journal of Business Administration
1982 - present

Program Co-Chairman
Second Annual Meeting of the International Association of Energy Economists
Churchill College, Cambridge University
Cambridge, England, June 22-24 1980

Research Associate
National Bureau of Economic Research
Productivity and Technical Change Program, and Health Care Program
1980 - present

Conference Co-Organizer (with Zvi Griliches), NBER Workshop on Measurement Issues, Investment, and Productivity
Summer 1983, 1984, 1986 - 1999; with others, 2000 - present

Associate Editor
Journal of Econometrics
April 1985 - February 1991

Associate Editor
Land Economics
April 1985 - February 1991

Member, Editorial Board
Journal of Economics and Management

Strategy
February 1991 - December 1998

Member, Editorial Board
Economic Inquiry
September 1991 - present

Other Professional Activities (Continued):

Member
Dean's Advisory Council
College of Business Administration
Valparaiso University
Valparaiso, Indiana
September 1985 - present

Conference Co-Organizer (with William Barnett and Halbert White)
Third Austin Symposium in Economics
University of Texas at Austin
May 22-23, 1986

Conference Co-Organizer (with W.Erwin Diewert and Jack Triplett)
Jubilee Anniversary of the NBER Conference on Research in Income and Wealth
Washington, D.C., May 12-13, 1988

Editor
Journal of Productivity Analysis
1987 - 1991

Member, Special Advisory Panel
National Science Foundation
Science and Technology Centers, 1988

Conference Co-Organizer (with Timothy Bresnahan, Zvi Griliches, and Marylin Manser), NBER Conference on Output Measurement in the Service Sectors, Charleston, South Carolina, May 3-5 1990

Conference Co-Organizer (with Peter Englund, Bengt-Christer Ysander and

Lennart Hjarmalsson), Productivity Growth in the Service Sectors, Uppsala, Sweden, May 22-24, 1991

Member, Advisory Panel
National Science Foundation
Measurement Methods and Data Improvement Programs, 1990

Other Professional Activities (Continued):

Economic Consultant and Academic Affiliate
Analysis Group, Inc.
Cambridge, MA, 1985 - present

Member, Advisory Committee on Service Statistics, Statistics Canada
Ottawa, Canada
December 1991 – February 2000

Member
Christ College, Alumni Advisory Board
Valparaiso University, Valparaiso, IN
January 1992 - present

Member, Committee of Visitors, Program in Economics, National Science Foundation
July 1992

Member, Research Consortium, Financial Executives Research Foundation, 1992 - 1995

Member, Editorial Board
Southern Economic Journal
July 1993 - present

Conference Co-Organizer (with Thomas W. Malone and Laurence C. Rosenberg) "The Productivity Impacts of Information Technology Investments," Charleston, South Carolina, November 11-13, 1993

Member, External Review Committee, Pennsylvania State University, Department of Economics, March-April, 1994

Appointed Representative of the American Economic Association to the U.S. Census Bureau Advisory Committee 1996 – 2000; co-chairman, 1999 - 2000

Member and Chair, National Bureau of Economic Research, Human Subjects Investigation Review Board, 1998 - present

Member, National Academy of Sciences Panel on the Conceptual, Measurement and Other Statistical Issues in Developing Cost-of-Living Indexes, 1999 - 2001

Member and Chair, Federal Economic Statistics Advisory Committee, 2000 – present

Member, American Economic Association, Committee on Economic Statistics, 2002 – present

Panel Review Member, National Science Foundation, Program on Methodology, Measurement and Statistics, Spring 2003 – present.

Intermittent Detail to the U.S. Food and Drug Administration, Office of the Commissioner, 5600 Fishers Lane, Rockville, MD 20857, October 1, 2003 – June 30, 2004.

Editorial Board, RAND Forum for Health Economics and Health Policy, March 2004 – present

Co-Director, MIT Biomedical Enterprise Program, July 2004 - present

Publications (in chronological order)

ARTICLES/CHAPTERS/REPORTS:

1. Berndt, Ernst R. and Laurits R. Christensen, "The Internal Structure of Functional Relationships: Separability, Substitution, and Aggregation," Review of Economic Studies, Vol. XL (3), July 1973, pp. 403-410.

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1976, pp. 59-68.

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Attachment B

OIG Reports Related to Medicare & Medicaid

Date	Report Title	Key Findings / Recommendations
Nov. 1992	"Physicians' Costs for Chemotherapy Drugs" (A-02-91-01049)	For a small, judgmental sample of NY physicians, OIG found that [13] chemotherapy drugs could be purchased at amounts below the established AWP, and that AWP was not a reliable indicator of cost. Recommendations include that HCFA (1) define reimbursement policy to encourage "most economical means" available for physician purchase of drugs; (2) revise coding and reimbursement systems to pay for drugs based on dosage actually administered. NB: Report noted that Equicore, the TN Medicare carrier, based payments for 5 chemo drugs on physician invoice prices.
Feb. 1996	"Medicare Payments for Nebulizer Drugs" (OEI-03-94-00390)	OIG examined differences in reimbursement methodologies between Medicare and Medicaid for 3 inhalation drugs in 17 states (1/94-2/95), finding that Medicare payments were considerably higher than those from Medicaid would have been due to (1) Medicare not using a discounted AWP, and (2) Medicare not having a drug rebate program with manufacturers. Recommendations included (1) use of a discounted AWP to establish drug prices (which would require revising Medicare's claims coding system to an NDC basis); (2) pursuing legislative options to establish a rebate program or competitive bidding process; (3) use the "inherent reasonableness" authority to set charge limits (would require streamlining that authority); (4) base payment on estimated acquisition cost (EAC) (although the regional carriers -- DMERCs -- had not been successful in gathering the necessary information). NB: Report made reference to OIG intent to examine other drugs that Medicare reimburses.
May 1996	"Appropriateness of Medicare Prescription Drug Allowances" (OEI-03-95-00420)	OIG compared Medicare and Medicaid drug payment methodologies for 17 physician-administered drugs (based on Medicare 1994 allowances for those drugs), finding that Medicaid's greater use of more heavily discounted AWP, and rebates, would have afforded lower prices than Medicare was paying. Recommendations were similar to those for nebulizer drugs, above. NB: With respect to Medicaid, the report also noted that states differed in their application of payment methodologies. More states used a discounted AWP to establish reimbursements to pharmacies than they did to physicians, meaning that some states used different discounting methodologies to reimburse pharmacy-dispensed vs. physician-administered drugs. Some states handled rebates differently for physician-administered drugs than for self-administered drugs.

Jun. 1996 (a)	"Suppliers' Acquisition Costs for Albuterol Sulfate' (OEI-03-94-00393)	OIG found that Medicare allowances for albuterol sulfate substantially exceeded suppliers acquisition costs. Same recommendations as for nebulizer drugs. HCFA concurred with recommendations, but noted that OMB did not approve a 1994 survey attempt to collect acquisition cost data because of burdensome nature of the task.
Jun 1996 (b)	"A Comparison of Albuterol Sulfate Prices" (OEI-03-94-00392)	OIG found that many pharmacies surveyed charged less than the Medicare allowance for albuterol, and that 5 buying groups surveyed had negotiated prices between 56 – 70% less than Medicare's reimbursement amount. Same recommendations as for nebulizer drugs.
Apr. 1997	"Medicaid Pharmacy – Actual Acquisition Costs of Prescription Drug Products for Brand Name Drugs" (A-06-96-00030)	OIG sampled Medicaid pharmacy providers in 11 states, comparing their actual invoices for drug purchases to AWP. OIG identified an average discount of 18.3% off AWP on a national basis (CY 1994), substantially larger than many states' reimbursement policies allowed (typically a 10% discount). OIG recommended HCFA work with states to ensure that reimbursement of the "ingredient portion" of Medicaid drug purchases was more in line with OIG's findings. [NB: Based on methodology, it appears that this analysis would have included primarily, and perhaps exclusively, self-administered drugs.] The report specifically refers to the June 1996 Barrons's article comparing AWP to actual acquisition costs, noting that industry insiders joked that AWP really meant "Ain't What's Paid".
Dec. 1997	"Excessive Medicare Payments for Prescription Drugs" (OEI-03-97-00290)	OIG focused on 22 drug codes representing Medicare's largest dollar outlays in 1995, and found that program and beneficiary payments would have been lower by 29% if reimbursements were based on actual wholesale prices rather than AWP. OIG specifically noted that published AWPs bore little or no resemblance to actual wholesale prices available to the physician and supplier communities. Medicare allowances were significantly greater than prices available thru wholesalers and Group Purchasing Organizations (gpos). OIG also found inconsistency in carriers' establishing and updating Medicare drug reimbursement amounts. Recommendations included (1) basing reimbursement on a more substantial discount off AWP than 5%; (2) pursing an actual or EAC option; establishing limits on increases in subsequent year price increases; (3) invoking the "inherent reasonableness" authority to set charge limits; (4) pursuing legislative options to establish rebates or competitive bidding; (5) standardizing reimbursement amounts for each HCPCS drug code.
May 1998	"Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs (A-06-97-00052)	OIG recommended that HCFA develop and submit a legislative proposal that would require drug manufacturers participating in Medicaid's outpatient Rx drug program to *pay Medicaid rebates based on AWP rather than on AMP* as provided by statute. OIG sought to reduce the anomaly of reimbursements to pharmacies being calculated relative to AWP while rebates were based on AMP. Manufacturers were

		inconsistent in their calculation of AMP, and OIG estimated substantial savings from aligning the rebate and reimbursement calculations. OIG recognized that there were problems with AWP but felt that, with certain safeguards, the use of AWP in rebate calculations could result in its being a more "meaningful and accurate number". HCFA did not believe that a legislative initiative was feasible, but agreed that changing from AMP to AWP would reduce an administrative burden. A March 2002 OIG report notes that President Bush's Fiscal Year 2003 budget proposed changing the basis for calculating rebates from AMP to AWP.
Jul. 1998	"The Impact of High-Priced Generic Drugs on Medicare and Medicaid" (OEI-03-97-00510)	OIG examined 4 drugs in which Medicare reimbursements were excessive because of the inclusion of high-priced generics (i.e., higher than brand prices) in the median generic price on which reimbursement was based. Re Medicaid (FL) – OIG examined 8 drugs for which reimbursements could have been less but for (1) inclusion of high-priced generics that (2) yielded lower rebates than branded drugs. OIG recommended the exclusion of higher-priced generics from median calculations used to determine reimbursement levels (Medicare), and restrict reimbursements by Medicaid to [pre-rebate] lower-priced brand or generic drugs.
Aug. 1998	"Are Medicare Allowances for Albuterol Sulfate Reasonable?" (OEI-03-97-00292)	OIG found Medicare allowances for albuterol substantially exceeded what the VA would pay for generic albuterol in 1998, and that mail order customers would pay up to 30% less than Medicare's allowances in 1998.
Nov. 1998	"Comparing Drug Reimbursement: Medicare and the Department of Veterans Affairs" (OEI-03-97-00293)	OIG examined 34 drug codes, for which Medicare payments were substantially greater than VA payments. In the absence of statutory reform, OIG recommended that HCFA invoke "inherent reasonableness" authority, and implement competitive bidding. HCFA noted that its DMERCs were recommending an 11% reduction in albuterol reimbursements, and that other drugs might be similarly reviewed. HCFA was subsequently challenged on the albuterol reductions, with "inherent reasonableness" authority put on hold.
Jun. 2000 (a)	"Medicare Reimbursement of Albuterol" (OEI-03-00-00311)	OIG compared Medicare reimbursements for albuterol with those of Medicaid and the VA, as well as with prices paid by chain and internet pharmacies. As with earlier reports, Medicare was again the outlier. Recommendations of previous reports were reiterated, with the notation that ability to invoke the "inherent reasonableness" authority had been limited by the 1999 Balanced Budget Refinement Act – GAO was to study the potential effects of using this measure before HCFA could invoke it. HCFA's response indicated it was moving to take advantage of DOJ and NAMFCU prices provided to First Databank, and was taking other actions including establishing a competitive bidding project in TX for albuterol purchases. The First DataBank prices were considered to be "more accurate data on average wholesale prices developed for Medicaid" as a result of a DOJ

		investigation.
Jun 2000 (b)	"Medicare Reimbursement of End-Stage Renal Disease Drugs" (OEI-03-00-00020)	OIG comparison of Medicare reimbursement of five ESRD drugs with that of Medicaid and VA. Similar findings, recommendations, and HCFA responses as above, with additional emphasis placed on HCFA's seeking legislative efforts to reduce its outlays.
Jan. 2001	"Medicare Reimbursements of Prescription Drugs" (OEI-03-00-00310)	OIG compared Medicare's reimbursement for 24 drugs (physician-administered or used with a nebulizer) with that of the VA, the physician/supplier community, and Medicaid. In addition to finding Medicare payments far exceeded those of the comparators, OIG noted that local Medicare carriers were not establishing consistent reimbursement amounts for certain drugs. In its response, HCFA noted that efforts to have its carriers use the DOJ's First DataBank AWPs had been hampered by legislation (H.R. 5543) that put a freeze on changes to AWP in use by Medicare as of 9/1/00.
Jul. 2001	"Cost Containment of Medicaid HIV/AIDS Drug Expenditures" (OEI-05-99-00611)	OIG compared Medicaid's net unit cost for antiretrovirals to that of other federal purchasers, and found that Medicaid paid from 5% - 33% more than the comparators. Part of the difference was attributed to different federally mandated formulae, however the discussion highlighted problems in determining an EAC, and the role of AWP manipulation in contributing to excessive payments.
Aug. 2001	"Medicaid Pharmacy - Actual Acquisition Costs of Brand Name Prescription Drug Products (A-06-00-00023)	OIG examined pharmacy actual acquisition costs of brand name drugs for 8 states, determining that the average discount off AWP for branded drugs was 21.84% for 1999 (an increase of 19.3% from their 1997 analysis for 1994 prices). However, this discount was greater than the discount allowed under most states' reimbursement policies. While AWP was not the basis for EAC in all states it was nonetheless predominant, with the average discount on a national basis being 10.31% of AWP. (OIG also compared WAC to actual acquisition price for pharmacies, and determined that invoice prices were, on a national basis, 1.81% below WAC.)
Mar. 2002 (a)	"Excessive Medicare Reimbursement for Ipatroprium Bromide" (OEI03-01-00041)	OIG compared Medicare reimbursements (based on AWP) for this inhalant product to prices paid by the VA, and to catalog and wholesaler/supplier prices. Medicare paid considerably more than any of the comparators, even though payments to 23 suppliers (accounting for 60% of Medicare payments) were presumably to outfits purchasing large quantities of the product (and thus able to attract manufacturer discounts).
Mar. 2002 (b)	"Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products (A-06-01-00053)	OIG examined pharmacy actual acquisition costs of generic drugs in 8 states, determining that the average discount off AWP for generic drugs was 65.93% for 1999 (an increase of 55% from their 1997 analysis of 1994 prices.) However, states' reimbursement methodologies did not allow them to capture much of this discount, and OIG recommended that reimbursements for ingredient costs be brought more in line with pharmacy acquisition costs. Since some states used WAC to determine reimbursement, OIG also examined WAC

		relative to acquisition cost, finding invoice prices averaging 30.55% below WAC. OIG felt that WAC was not a true wholesale acquisition cost and was significantly higher than actual acquisition costs for generic drugs. OIG also cited a 1984 report in which it found that pharmacies purchased drugs at 15.9% below AWP, and a 1989 report showing a 15.5% discount. However, these reports combined brand and generic drugs. The cover letter to this report references the Bush FY 2003 proposal to use AWP rather than AMP in rebate calculations.
Sep. 2002	"Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products (A-06-02-00041)	A follow-up to the March 2002 report, OIG extended their analysis of discounts off AWP for additional drug categories, including single and multiple source innovator drugs, and drugs with and without federal upper limits (FULs). OIG found wide variation in prices paid by pharmacies, with average discounts off AWP ranging from 17.2% for single source innovator drugs to 72.1% for multiple source drugs with upper limits. OIG recommended that for states that continued to reimburse for drugs based on AWP, a four-tiered reimbursement methodology be introduced that better captured the within-category fluctuations in actual discounts: (1) single source innovator drugs; (2) all drugs without FULs; (3) multiple source drugs without FULs; (4) multiple source drugs with FULs. Without evaluating CMS' FUL prices, OIG also observed that drug manufacturers appeared to provide steeper discounts off AWP for drugs with FUL listings. Finally, OIG reiterated their recommendation that AWP be substituted for AMP in calculating rebates due from manufacturers.
Jan. 2004 (a)	"Update: Excessive Medicare Reimbursement of Albuterol" (OEI-03-03-00510)	Another comparison of Medicare reimbursements vs. Medicaid payments for albuterol. Findings similar to above; some additional discussion about DMERCs charged with determining reimbursement methodologies in their respective regions, based on Medicare methodology.
Jan. 2004 (b)	"Medicare Reimbursement for Lupron" (OEI-03-03-00250)	OIG discusses a "local medical review policy ("LRMP") whereby Medicare carriers apply a "least costly alternative" standard in determining reimbursement. Specifically, OIG reviewed jurisdictions' application of that standard with respect to Lupron being covered at the less expensive Zoladex price, and found that not all jurisdictions were applying the standard.
Jan. 2004 ©	"Update: Excessive Medicare Reimbursement for Ipatroprium Bromide" (OEI-03-03-00520)	Update of 2002 OIG comparison of Medicare reimbursements for this inhalant relative to those of Medicaid and the VA.
Sep. 2004	'Variation in State Medicaid Drug Prices" (OEI-05-02-00681)	For 28 drugs, OIG found considerable variation across states in reimbursement rates, with prices varying more for the 10 non-innovator drugs than for the 18 innovator products. Comparable estimated acquisition cost formulae (e.g., AWP-10%) might still yield very different prices. There were also

		differences in setting "U&C" charges as well as MAC.

All reports accessed through www.oig.hhs.gov/reports.htm.

Attachment C

Other Uses of AWP

Manufacturers frequently sponsor or support pharmacoeconomic studies that compare the cost-effectiveness of alternative medical treatments, sometimes among pharmaceuticals, and other times involving comparisons of therapies combining pharmaceutical and non-pharmaceutical components. In the well-known National Institutes of Health convened consensus guideline compendium for conducting cost-effectiveness studies, the following recommendation is made concerning what prices should be used when evaluating pharmaceutical costs:

> "Because the class of drugs must break even – have revenues large enough to cover R&D, production and distribution costs – prevailing transactions prices will usually act as a serviceable way to value consumption of the drugs. The Average Wholesale Price (AWP), which approximates prices in discount pharmacies, is one source of such information (Drug Topics Red Book, 1994)."[299]

Note that to the extent AWPs approximate the cash prices paid by retail pharmacy customers (which is not an uncommon assumption, as I noted in the main text), this recommended use of AWP is understandable. However, because cash prices at retail pharmacies are typically much greater than pharmacy reimbursements received from third party payors (plus patient copayments), and since cash transactions are a small and declining portion of all retail transactions (less than 15% of prescriptions in 2002 and 2003),[300] the recommended guideline use of AWP overstates average prescription drug costs to third party payors. Hence, to the extent

[299] Marthe R. Gold, Louise B. Russell, Joanna E. Siegel and Milton C. Weinstein, eds., *Cost-Effectiveness in Health and Medicine*, New York: Oxford University Press, 1996, p. 195. A summary of these guidelines was published by the authors under the title "Recommendations for Reporting Cost-Effectiveness Analysis", *Journal of the American Medical Association* 276, No. 16 (1996), pp. 1339-1341.

[300] Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*," Abt Associates Inc., August 30, 2004, p. 12.

manufacturers "artificially inflate" AWPs, other things equal, the measured cost-effectiveness of their products is likely to be reduced.

Evidence suggests drug manufacturers are increasingly employing economic messages in prescription drug advertisements in medical journals. A recent study reports that the proportion of ads with economic content in six leading general medical and specialty journals increased between 1990 and 1999.[301] When assertions were made that a drug was "less expensive" or "costs less", 92% of the advertisement provided supporting evidence. According to the authors:

> "Supporting evidence pertained mostly to the average wholesale price of drugs (51.1%) or to published drug prices in the Red Book (38.7%). Other sources included 'data on file' (9.5%) and references to published studies (6.6%)."[302]

Of related interest is the FDA's policy on what price comparisons it permits in manufacturers' promotional material, and what types of economic claims the FDA considers false or misleading.

One recent analysis of FDA actions analyzed all public letters sent by the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") to drug companies in which promotional violations involving economic claims were cited. Of the 28 warning letters and notices of violation between January 1997 and December 2001, five (17.9%) involved misleading price comparisons.[303] According to the authors, two DDMAC citations involving misleading price comparisons were as follows, with both explicitly lacking support by reference to AWP:

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[301] Peter J. Neumann, Kara Zivin Bambauer, Vijay Ramakrishnan, Kate A. Stewart and Chaim M. Bell, "Economic Messages in Prescription Drug Advertisements in Medical Journals", *Medical Care*, 40:9, 2002, pp. 840-845.
[302] Peter Neumann et al. [2002], supra, p. 842. A footnote appended after the words "Red Book" referenced: "Drug topics, Red Book. Montvale, NJ: Medical Economics; 1999."
[303] Kate A. Stewart and Peter J. Neumann, "FDA Actions against Misleading or Unsubstantiated Economic and Quality-of-Life Promotional Claims: An Analysis of Warning letters and Notices of Violation", *Value in Health*, 5:4, 2002, pp. 390-397.

> "…comparative pricing claims are misleading because they lack adequate context…The cost effectiveness claim is misleading because the claim is not supported by reference to AWP."
>
> "The comparative price/cost conclusion of a '47% difference' is misleading because the above price/cost comparison is based on an undefined time frame and therefore the conclusion of a 47% difference suggests a greater savings than what is supported by AWP data."[304]

Other uses of "artificially inflated" AWPs are likely to have negative impacts on pharmaceutical manufacturers. Critics of the pharmaceutical industry, such as Families USA, frequently criticize the industry for raising its prices, and document such price increases by publishing annual changes in manufacturers' AWPs.[305] To the extent AWPs are "artificially inflated", manufacturers are likely to face increased amounts of adverse publicity. Finally, health data information firms such as IMS Health produce data on, among other costs, the marketing costs of prescription drug manufacturers. Critics of the industry frequently cite the pharmaceutical industry as having excessive marketing costs.[306] By convention, IMS Health reports that approximately one half of pharmaceutical "detailing" promotional costs (office visits by sales representatives to physicians) consist of free samples left physicians. These free sample costs are calculated by valuing the free samples at average retail value. It is my understanding

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[304] Stewart and Neumann, "Analysis of FDA Regulatory Actions" [2002], *supra*, p. 397.

[305] See, for example, *Sticker Shock: Rising Prescription Drug Prices for Seniors: A Report by Families USA*, June 2004, available online at www/familiesusa.org/site/DocServer/Sticker_Shock.pdf?docID=3541. Accessed 1/23/05. Notes to Table 1 refer to Medi-Span's MDDB Select, published by Medi-Span, as a data source. An earlier Families USA publication provides more details: see *Worthless Promises -- Drug Companies Keep Boosting Prices: A Report by Families USA Foundation*, March 1995. On page 9 it is stated: "The price increase data in this report is based on price increases in average wholesale prices. This list price is set by manufacturers as the suggested price a wholesaler should charge a retail pharmacy. Since nearly all retail pharmacies use the AWP to determine a prescription's retail price, this price provides an accurate reflection of the price increases that consumers face when they purchase prescriptions in retail pharmacies and pay out of pocket. The Medi-Span Master Drug Database of drug prices provided average wholesale price information for the most frequently dispensed outpatient strengths and package sizes of drugs."

[306] See, for example, Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What To Do About It,* New York: Random House, 2004. See, for example, chs. 8 and 9. On p. xviii, she calls the pharmaceutical industry "primarily a marketing machine to sell drugs of dubious benefit".

that the AWP is used as the measure of average retail value, but I have not been able to confirm that.[307]

Finally, although to date the recommendation has not been adopted, the Department of Health & Human Services, Office of Inspector General, has endorsed the CMS' legislative proposal that Medicaid prescription drug rebates from drug manufacturers be calculated on the basis of AWP rather than the average manufacturer's price ("AMP"). Unless the rebate proportion would change as well, such a policy change would likely "result in AWPs that more closely reflect the actual acquisition cost of a given drug."[308]

[307] Meredith B. Rosenthal, Ernst R. Berndt, Julie M. Donohue, Richard G. Frank and Arnold M. Epstein, "Promotion of Prescription Drugs to Consumers", *New England Journal of Medicine*, 346(7), February 14, 2002, pp. 498-503.
[308] Office of Inspector General, *Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products*, Report A-06-02-00041, September 2002, p. 11.

Attachment D

Ownership of Top PBMs – Quarter 1, 1999

Rank	PBM Name	Owner Type (a)	Comments
1	Merck Medco Managed Care	Pharmaceutical firm	Medco Containment Services founded as a mail order prescription firm, substantial growth after investment by Martin Wygod (1983); purchased by Merck in 1993; spun off from Merck in 2003
2	PCS Health Systems	Retail Chain	Eli Lilly purchased PCS, the nation's largest managed pharmaceutical care company, from McKesson in 1994 and then sold to Rite Aid in 1998. Sold by Rite Aid to Advance Paradigm in 2000.
3	Diversified Pharmaceutical Services	in transition to PBM parent from pharmaceutical firm	Founded by United Healthcare, then incorporated in 1988; sold to SmithKline Beecham in 1994. Acquired by Express Scripts in 1999.
4	Express Scripts/Value Rx	Independent	Founded in 1986, brought public in 1992 after being spun our of New York Life. Acquired Value Rx from Columbia / HCA Healthcare Corporation in 1998. Acquired DPS from SmithKline Beecham in 1999.
5	Aetna Pharmacy Management	Insurance company	
6	Advance Paradigm	Independent	Incorporated in July 1993 as a wholly owned subsidiary of Advance Health Care, which then merged into Advance Paradigm before a public offering in 1996. Acquired Integrated Prescription Solutions in 1999 and PCS Health Systems in 2000. Purchased by Caremark in 2004.
7	Wellpoint Pharmacy Management	Health Plan	Founded in 1992 to operate Blue Cross of California's managed care business, spun off in 1993 as a separately traded public entity. Became part of Anthem, Inc. in 2004, with Anthem adopting the Wellpoint name.
8	RxPrime	Insurance company	Cigna's managed PBM, formed in 1992
9	Caremark Prescription Services	Independent	Established as a division of Baxter Healthcare Corp. in 1985. Purchased Prescription Health Services in 1991; spun off from Baxter in 1992.

10	Prescription Solutions	Independent	Founded in 1993 by pharmacists for managed care.
11	National Prescription Administrators	Independent	Originally founded and operated by pharmacists (c. 1978); acquired by Express Scripts in 2002.
12	ProVantage	Retailer	Launched in 1993 as a ShopKo (discount chain) subsidiary; purchased by Merck Medco in 2000.
13	MedImpact / MedCare	Privately held	MedImpact was founded in 1989; considered the "largest privately held PBM in the nation". MedCare is MedImpact's national formulary.
14	Prudential Pharmacy Management	Insurance company	
15	Prime Therapeutics	Independent	Created in 1998 by merger of Pharmacy Gold Inc. and ProPar Services; in 2005 several Blue Cross / Blue Shield plans joined together to acquire an ownership interest in Prime.
16	Eagle Managed Care	Retail chain	Rite Aid's PBM subsidiary, which merged with PCS Health Systems when Rite Aid purchased that firm in 1999.
17	Proserve	n/a	Name linked with Wellpoint but other information not found.
18	RxAmerica	Retail chain	Began managing Rx programs ~20 years ago as American Drug Stores (now Albertsons); officially formed as a PBM in 1994. Longs Drug Stores and American Drug Stores merged PBM operations in 1997, calling the venture RxAmerica.
19	PharmaCare Network	Retail chain	Founded in 1994; a wholly owned subsidiary of CVS
20	RESTAT	Wholesaler	Founded c. 1985; part of The F. Dohmen Company, a "nationally recognized pharmaceutical service, distribution, and software consultant".

(a) At time of ranking
n/a: no information available
Source of PBM ranking: The Role of PBMs in Managing Drug Costs: Implications for a Medicare Drug Benefit. Prepared by Mathematica Policy Research, Inc. for The Henry J. Kaiser Family Foundation, January 2000. Available online at www.pharmacy.ca.gov/publications/pbm_kff_role.pdf, last accessed 1/28/05.
Other websites consulted for additional information on each ranked PBM are listed on the next page.

Websites accessed 1/28/05:

www.utsystem.edu/egi.newsletter
www.primetherapeutics.com/abouthistory.htm
www.medimpact.com/About_MedImpact/default.asp?subpage=background
www.restat.com/information/index.cfm
http://sec.edgar-online.com/1996/09/30/00/0000912057-96-021465/Section11.asp
www.caremark.com/wps/portal/_s.155/3359?cms=CMS-2-003599
www.anthem.com/jsp/antiphona/apm/primary.jsp?secp=AboutUs
www.rxsol.com/a/about/aboutus.asp
www.pharmacare.com/about/index.jsp
www.delta-hq.org/publications/AllAboutCVS.pdf
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www.wellpoint.com/business/company_history.asp

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www.sec.gov/Archives/edgar/data/1012956/0000912957-96-013211.txt
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